

1 UNITED STATES DISTRICT COURT  
2 FOR THE NORTHERN DISTRICT OF OHIO  
3 EASTERN DIVISION  
4  
5 IN RE: NATIONAL )  
6 PRESCRIPTION OPIATE ) MDL No. 2804  
7 LITIGATION ) Case No. 17-md-2804  
8 ) Judge Dan Aaron Polster  
9 THIS DOCUMENT RELATES TO: )  
10 Track Eight )

11  
12 HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER  
13 CONFIDENTIALITY REVIEW

14 ZOOM VIDEOTAPED DEPOSITION OF  
15 FRED OTTOLINO  
16 (Taken by Plaintiffs)

17  
18 December 6, 2022

19  
20 9:04 a.m.

21 Deposition held via Zoom Videoconference

22  
23 Reported by:  
24 F. Renee Finkley, RPR, RMR, CRR, CLR, CCR-B-2289  
25 (Via Videoconference)

1           A.       Yes.

2           Q.       Do you have an understanding of whether  
3     the pharmacy itself has a responsibility with respect  
4     to its pharmacist to be sure that they only dispense  
5     prescriptions pursuant to a legitimate medical  
6     purpose?

7                   MR. HUDSON:  Objection, form.

8                   THE WITNESS:  I think that the pharmacy's  
9     role is to give the pharmacist the tools they  
10    need to use good judgment and make a good  
11    decision.  So if it's some -- this memo would be  
12    an example, I would think, of that, that we  
13    educate the pharmacist of different issues make  
14    sure they're up to speed on those decisions.

15                   Ultimately, that pharmacist has the right,  
16    and we would not override the right, might offer  
17    guidance, but we would not override the  
18    pharmacist decision to dispense or not dispense.  
19    It's his professional judgment that makes that  
20    decision, so I hope that answers your inquiry.

21           Q.       (By Ms. Conroy)  No, I think it does.  And  
22    let me just state it a little differently, and see if  
23    you agree with me, that Publix as the pharmacy and  
24    you as vice president of pharmacy operations, you  
25    have a responsibility to provide your Publix

1           The -- depending on the situation, there  
2           are -- I would need an example from you about  
3           what specifically the pharmacist was doing that  
4           would be in question. But if you could give me  
5           that, I could maybe share some more information  
6           regarding what our system was capable of doing.

7           Q.       (By Ms. Conroy) Sure. Let me try and do  
8           that. If a -- you brought up the term red flags in  
9           the first session. And let's see. Something that a  
10          pharmacist might look at was or may hear back from  
11          switch, for example, that a doctor did not have a DEA  
12          number. And I know there are some -- or what did you  
13          say a P -- there's some other number they may not  
14          have. I know that there's a difference over time.

15                 Let's say that came up. Is there any way  
16          for the pharmacy supervisor, or the pharmacy  
17          operations manager, or someone to audit whether or  
18          not a pharmacist is taking those steps, is making  
19          sure, for example, that there is a valid DEA number  
20          for a physician who has written a prescription for a  
21          controlled substance?

22          A.       Well, the system itself would remedy that  
23          situation, because that prescription could not be  
24          processed. So if I do not have a legitimate DEA  
25          number, it's a hard stop. They cannot process that

1     prescription and get that -- get a label out of the  
2     computer, if you will, to label a prescription and  
3     dispense that medication.

4             Q.     Is there any way around that?

5             A.     No.

6             Q.     Okay. So that -- that's probably not the  
7     best example, then, because it wouldn't be any -- the  
8     supervisor wouldn't have to check to see if anything  
9     was happening correctly, right? Because it couldn't  
10    dispense that prescription. That decision would be  
11    made for the pharmacist, correct?

12            A.     Yes, the system would block it. There's  
13    no need for a supervisor to intervene in that case.  
14    So those examples of a wrong DEA number is pretty  
15    much -- I'll say a no -- it's pretty simple. If you  
16    don't -- the rule is, if you don't have a DEA number  
17    in the system, you can't -- you cannot dispense that  
18    medication.

19            Q.     Are you familiar at all with the term  
20    dummy DEA numbers?

21            A.     I've heard of that, yes.

22            Q.     Do you know what that is?

23            A.     Yes.

24            Q.     Do you know if that's a way to go around  
25    the -- the system that does not allow a prescription



1 over -- looking over the whole operation. That would  
2 help them make that determination, if there's  
3 something that they have to review at the local  
4 pharmacy.

5 Q. And would those exception reports include  
6 outliers with respect to controlled substances?

7 A. Yes.

8 Q. They could?

9 A. Oh, they did. Not all of them.

10 Q. Yeah.

11 A. Yeah. I mean, yes, we had a number of  
12 different reports that we looked at, and guardrails  
13 if you were -- we had reports that showed  
14 prescriptions -- that red flag comment, quite  
15 frankly, that if we saw a location that had higher  
16 percentage of controlled drugs on a controlled drugs  
17 versus total drug basis, that location would be red  
18 flagged. And the supervisor would be charged to  
19 examine that location, and understand why.

20 And some --for instance, a new store might  
21 open. And typically, with new pharmacies, it takes  
22 time to build that business. So you might fill a  
23 very low number of prescriptions to begin with. And  
24 you fill a couple controlled substances, that  
25 percentage basis is out of line with the norms,

1     whatever that norm was, I can't remember what percent  
2     that was.

3                     So that would stand out. And then that  
4     would be easily understood. There might be a new  
5     physician that comes into a certain market that  
6     changes the dispensing mix. We had inventory control  
7     pieces that would show us that also. So there's a  
8     number of different reports that we could look at  
9     that would help our supervisors manage these  
10    pharmacies, oversee these pharmacies.

11            Q.     And what would you call those reports that  
12    would, for example, look at the percentage of  
13    controlled versus non-controlled for a particular  
14    pharmacy, do you remember?

15            A.     I can't remember the exact same of that  
16    report, but there were a number of  
17    different -- number of different parameters that were  
18    measured on one specific report I remember. I can't  
19    recall the exact same of it, or the file name.

20            Q.     Okay. And would those make their way to  
21    your desk or was that someone else's responsibility  
22    who reported to you?

23            A.     That was more the responsibility of our  
24    operations team. I would be cc'd on those reports,  
25    but I would not -- I wouldn't -- unless there's

1 something so egregious that I can't think of a time  
2 that that was, to be honest with you, but that was  
3 the responsibility of our operations team.

4 Q. Okay. And do you recall how often those  
5 -- was there a set, you know, once every two weeks or  
6 once a month, those reports would be generated? And  
7 I'm talking specifically about the percentage of  
8 controlled versus non-controlled if that's helpful to  
9 you.

10 A. I don't know exactly how -- it was  
11 frequent enough that we would catch trends if there  
12 was a trend, so -- and just to be clear, there were a  
13 number of different, I'll say red flags on that  
14 report. It wasn't just a percent of controlled  
15 substances. Another flag would be the amount of cash  
16 paying customers for controlled substances.

17 Q. And why would it be important to watch  
18 trends with respect to that?

19 A. Why would it be important to watch a  
20 trend? So you know which direction the pharmacies --  
21 so they don't get down the wrong path, right?

22 Q. Yeah. With cash, so would more cash or  
23 less cash, what does that mean, if it were trending?

24 A. Yeah, so the theory behind that is -- and  
25 I can't remember the percent, you'll have to forgive

1 me. But the vast majority of prescriptions are paid  
2 through a third-party insurer. Cash business has,  
3 over time, dwindled. So back in '70s, it was king.  
4 Now, everybody has --

5 Q. Do you have any cash in your wallet,  
6 Mr. Ottolino? Probably not.

7 A. The answer is no, you know, so -- but the  
8 bottom line is insurance companies pay for a lot of  
9 these prescriptions, so you would expect that same  
10 percentage to go across the board on controls and  
11 non-controls.

12 So if a store had a higher percentage of  
13 -- they might have a higher percentage, 'cause it  
14 might be like -- and I'm making these numbers up, 4  
15 percent, 4 and a half percent, so technically, 4 and  
16 a half is higher than 4, but if they had, I'll say  
17 20 percent cash on -- 20, 25, don't quote me on that  
18 number, I would have to look at that document, I  
19 guess, and see what that percent is.

20 But if there was a number of cash  
21 prescriptions that were higher, that would indicate,  
22 okay, Well, why would that be. And maybe that is,  
23 you know, people trying to get outside the insurance  
24 companies' purview and have excess prescriptions for  
25 controls.

1           Q.     And would that be potentially a red flag  
2     for diversion?

3           A.     I think that's why we had that report set  
4     up.

5           Q.     And would those trends be available to a  
6     pharmacist in a local pharmacy, would they be able to  
7     see what those trends look like?

8           A.     Yes.

9           Q.     At their pharmacy?

10          A.     Yes.

11          Q.     And how would they see those? Was  
12     it -- was it e-mailed to them, or was it something  
13     that was available at the store level, or how would  
14     they know?

15          A.     Well, definitely through their supervisor.  
16     Now, I can't speak to the fact that those reports  
17     were e-mailed to the specific store location, but I  
18     would -- I know definitely it was a report that our  
19     supervisors would oversee and distribute as needed.

20          Q.     Okay. Let's take a look next at -- it's  
21     in your box. I'm looking at P-19738. Sarah or Laura  
22     may be able to tell you which box. It's on the  
23     screen. This one does not have a P-PUB number. It's  
24     just going to say P-19738-0001.

25                 MR. HUDSON: Is that the second box?

1     trying to recall if there was situation where -- I  
2     would have to see documentation about what was in  
3     place if there's any documentation regarding, if it  
4     ever happened, regarding controlled -- I don't -- I  
5     don't know the answer to that.

6           Q.     Okay. So at least -- and I know it's been  
7     some time, but as you sit here today, nothing comes  
8     to mind of any situation at any Publix pharmacy that,  
9     you know, you oversaw as vice president, where there  
10    was any diversion of controlled substances, nothing  
11    is coming to mind?

12          A.     I think that goes back to your previous  
13    question of not having to report anything. I know  
14    that -- or was I surprised that there's no reporting.  
15    I think that I answered no. I think that's because  
16    of what we had in place. So we had policy  
17    council -- not policy council. So we had compliance  
18    meetings on a quarterly basis. And I know that was  
19    one of the parameters that was measured, to make sure  
20    that we were doing things the right way. And that  
21    never came up, to my recollection, my recall,  
22    in -- in those meetings or any -- anything that we  
23    discussed, that would be a metric that we would  
24    measure.

25                   So that's the impetus of my answer behind

1     that one, it's -- and if you go down to how bacteria  
2     travels, it talks about sneezing and dripping water,  
3     and things like that. Do you see that?

4             A.     Yes, I do.

5             Q.     In other words, was it -- was it a goal of  
6     yours as vice president of pharmacy operations that  
7     the guidelines be useful and helpful to the employees  
8     of the pharmacy?

9             A.     Yes.

10            Q.     And would -- pharmacists would receive  
11    these, correct?

12            A.     This was in every pharmacy.

13            Q.     And would the -- when you say it was in  
14    every pharmacy, was there a hard copy of the  
15    guidelines in every pharmacy?

16            A.     Yes, eventually, we got to electronic  
17    copy, but there originally was a hard copy in every  
18    location.

19                   MS. CONROY: Okay. And if we could then  
20    go to, Gina, 359.

21            Q.     (By Ms. Conroy) And this one, I'm going  
22    to show you some dates, if we could mark this as the  
23    next exhibit.

24                   (Exhibit 5 was marked for  
25    identification.)

1 judgment analysis of the pharmacist to determine  
2 whether a prescription is legitimate?

3 A. The valid -- the pharmacist, in his or her  
4 judgment, good judgment, should look for invalid  
5 prescriptions. If one of these potential bullet  
6 points are listed, it gives the pharmacist reason to  
7 question.

8 So I'll play devil's advocate on that  
9 first bullet point, that the prescriber's practice is  
10 not where the patient resides. Well, if they're  
11 going to Cleveland Clinic to see a specialist and  
12 they live in Georgia, that could be a legitimate  
13 prescription, a valid prescription.

14 But this is a guide for the pharmacist  
15 that if they have -- to make sure they think things  
16 through as they fill a prescription. It's not the  
17 end all, it's not an absolute. There's -- you could  
18 probably go through each of these and come up with  
19 gray for each of these. It's the pharmacist's  
20 judgment that -- that is needed in filling these  
21 prescriptions.

22 Q. I think actually you had a great term for  
23 it. You said these are just clues, they don't  
24 necessarily mean it's not a legitimate prescription,  
25 but it's a clue that the pharmacist should maybe take



1           A.       Yes, ma'am.

2           Q.       And then she says, we have centralized the  
3       identification and evaluation of orders of interest  
4       to the pharmacy compliance department.

5                   Do you see that?

6           A.       I do see that.

7           Q.       Now, you did not have a pharmacy  
8       compliance department during your tenure, correct?

9           A.       That is correct.

10                  MR. HUDSON:  Objection, form.

11          Q.       (By Ms. Conroy)  So this is -- that's new  
12       now, a pharmacy compliance department at Publix  
13       sometime after you left in early 2018?

14          A.       We had a compliance team that met  
15       quarterly back from -- I want to say '05.  I think it  
16       was some early time frame.  So we had the function.  
17       Do we have a separate department -- and I'm assuming  
18       this -- I don't even know if this is within the  
19       pharmacy department itself, or where it is.  So the  
20       structure might be different, but the function was  
21       there.

22          Q.       Okay.  To be fair, you don't know what the  
23       function of the pharmacy compliance department is or  
24       was after you left, right?

25          A.       That is true.  I'm assuming through the

1 a listing of our stores and -- not a snapshot  
2 history, a summarization of what the stores were  
3 dispensing. And bounced up against certain red  
4 flags.

5 So I mentioned two of them that I recall.  
6 One is the percent of controlled substances over the  
7 total number of prescriptions. So if the store had a  
8 higher percentage of -- again, I'm going from memory  
9 here, so it's kind of hard for me to give you the  
10 precise details, but if the store had a higher  
11 percentage of controlled substances percent over  
12 total scripts than other stores, or whatever  
13 threshold we put in place, that would be something  
14 that the supervisors would see on this report.

15 And those cells would be highlighted, hey,  
16 look at these stores for this issue. And there would  
17 be a number of issues, cash prescriptions, I  
18 mentioned the other -- if there's a lot of cash  
19 prescriptions. There's another thing, hey, if  
20 there's a high percentage, look at that. And there  
21 might be some logical explanations. Again,  
22 everything is not black and white, that the high  
23 percentage of controlled substances to -- compared to  
24 total scripts might be high because it's a new store.

25 New stores inherently have lower total

1           A.       I don't have that.

2           Q.       No, that's okay. Just would have been a  
3       little bit easier for you with the size. This one  
4       that's up on the screen, and we can try to do it on  
5       the screen, and then we'll -- it might be in that  
6       third box that you got.

7           A.       Oh, good thought. Let me try and look at  
8       that. You are correct. It isn't cash, it is more  
9       files. 435-A is in this one here.

10          Q.       Terrific. Okay. So we'll mark that as  
11       the next exhibit.

12                   (Exhibit 13 was marked for  
13       identification.)

14          Q.       (By Ms. Conroy) And -- and what I -- I  
15       will represent to you these are some of the team  
16       meeting notes pulled out. So we know that the first  
17       page is October 31st of 2006, but we know that there  
18       were compliance team meetings before that, okay? So  
19       we know this wasn't the first one, but it happens to  
20       be the first one in this exhibit. Then if we look at  
21       the very first paragraph, the introduction, Karl  
22       Zillgitt, apparently, is writing these. Who is Karl  
23       Zillgitt?

24          A.       Karl Zillgitt was an attorney, might still  
25       be. At the time, he was an attorney for Publix and

1 he led the compliance team meetings for us.

2 Q. At least as of October of 2006, he says, I  
3 met with Fred Ottolino, Jillanne Smith, and Steve  
4 Resnick for the third quarter 2006 pharmacy  
5 compliance team meeting. So the compliance team at  
6 that point was Karl, you, Jillanne, and Steven  
7 Resnick, correct?

8 MR. HUDSON: Objection, form.

9 THE WITNESS: Yeah, so there's -- those  
10 are the people that met at this meeting. Steve  
11 Resnick is an attorney or was an attorney,  
12 excuse me, for Publix. We had people in  
13 different roles. And I think if we go through  
14 all these documents, you could see who was in  
15 that meeting at different times. There's some  
16 turn over of people that they came in, came out,  
17 different representatives, and so forth. So the  
18 people, assuming the document is accurate, I  
19 don't know why it wouldn't be, those are the  
20 people that attended the meeting.

21 Q. (By Ms. Conroy) Was there an actual  
22 compliance team or was it something that various  
23 people would be called upon to be on the team for  
24 certain projects at certain times?

25 A. Consistently, Karl, Jillanne, and myself

1     were on the team from the onset. We thought it was  
2     important to have Steve Resnick on the team at the  
3     time because Steve Resnick was the attorney within  
4     Publix that represented pharmacy or was focused --  
5     one of his focuses was at least I could say was on  
6     pharmacy.

7                 So we had him join. We had other people  
8     whose names escape me. The topic was that we need  
9     more information on or more -- just more information  
10    on, we would have that person show up to the meeting  
11    to discuss their metrics that -- or the metrics that  
12    were presented for that quarter.

13            Q.     And the people on the compliance team or  
14    invited to participate in compliance team meetings,  
15    they had other jobs at Publix as well, right?

16            A.     Yes.

17            Q.     Now, it says --

18            A.     I did -- I'm sorry to interrupt, but just  
19    for clarity, I know that John Attaway, who's our --  
20    who was the lead general counsel at the time was our  
21    compliance officer for the company. So I don't know  
22    if that helps you with your -- your inquiry.

23            Q.     Okay. Now, it says here that the purpose  
24    of the meeting, and I assume they're talking about  
25    the October 2006 meeting, was to determine the status

1 of Publix's compliance with applicable laws and  
2 regulations, and to determine whether Publix met its  
3 goals under the pharmacy metrics during the quarter.  
4 What -- what were the pharmacy metrics? What was  
5 that?

6 A. I'm surprised it's not in here, to be  
7 honest with you, but there would be a document that  
8 we would gather data for different factors that  
9 affect us legally to make sure that we were  
10 compliant, so -- or things that we wanted to have  
11 accomplished. One of the things that were, I think  
12 -- I'm surprised that's not attached to this, 'cause  
13 I could speak to the --

14 Q. Well, it says a copy of the metrics is  
15 attached along with the third quarter results as  
16 provided by the pharmacy department and legal  
17 department. I don't know we actually had them, but  
18 we can -- folks will look and see if we have it, or  
19 we may come across something that is in the document,  
20 but there would be an actual metric that would be  
21 attached to the minutes or discussed during the  
22 meeting?

23 A. Yeah, it was a page or two of different  
24 metrics. You can get a sample of that if you go a  
25 little bit deeper into this folder, you could see a

1 cut out of that metrics, and I don't know how to --

2 Q. Is that on Bates number 705?

3 A. Yes.

4 Q. Bottom right?

5 A. Yeah, I see that. So this is about  
6 product tampering and prescription files. We had  
7 things regarding training on there. We set up  
8 metrics to see if we were in -- what a goal would be.  
9 You see the hazard there, and who was the reporter of  
10 that on that -- that information where we got the  
11 information from.

12 And then we would fill out that last  
13 column to say that whatever comments we had, whatever  
14 we discussed at that meeting were in good standing.  
15 Let's see if we could tighten the goal become even  
16 better, what do we need to make sure that we obtain  
17 the goals, stuff like that was -- was communicated  
18 during this meeting.

19 Q. Okay. And when it says you would have a  
20 goal and then moderate hazard or severe hazard,  
21 that's a determination that someone would make when  
22 there was a report of a particular problem whether it  
23 was a moderate or severe hazard?

24 MR. HUDSON: Objection, form.

25 THE WITNESS: We would use that within the

1 meeting to see where Publix was. So obviously,  
2 if I look at that, the number of board pharmacy  
3 notice violations, the goal would be zero. If  
4 we had, you know, one violation, okay. Well,  
5 and we had a one off situation, if we had a  
6 hundred of them which we wouldn't put a hundred  
7 as a severe piece, but that's just for example.  
8 Okay, we have issue here we have to address.  
9 What is it that boards of pharmacy are coming?  
10 Do we not have the right signs up in our  
11 pharmacy? What is it that a certain inspector  
12 is seeing in our stores that we need to -- to  
13 get addressed. So it's just a way of making  
14 sure that across many different disciplines in  
15 pharmacy, that we were on the right page.

16 Q. (By Ms. Conroy) And the -- the pharmacy  
17 metrics, where were those kept? Where was that data  
18 housed?

19 A. Oh, that depends on the metric. Matter of  
20 fact, on this sheet, you could kind of see it.  
21 There's the last one was we had QREs, quality related  
22 events, dispensing errors is basically what that  
23 means. So we would know in that database, pharmacy  
24 was the owner, that's the next column over. So  
25 pharmacy was responsible for pulling that data and



1 presenting it in this meeting the pharmacy team.

2 Q. Okay. And let's say we're talking about  
3 this one failure to maintain patient profiles and  
4 prescription files, and that's owned by pharmacy  
5 and --

6 A. Yes.

7 Q. Somebody at some point, there's going to  
8 be a benchmark put in there, either going to be zero  
9 or whatever it is. Where -- would that data just  
10 keep -- would someone just keep up with that in the  
11 matrix and at each team meeting, when it became a  
12 topic, you could go to that column, and that row and  
13 see how things were progressing?

14 A. Yeah. So typically, what happened in the  
15 meeting is that we would have this -- or this metric  
16 sheet, and we would monitor our one benchmark goal if  
17 we hit the goal. If not, we would look back at a  
18 previous meeting. Are we training in a good or bad  
19 way? Are we reducing our hazard if the goal was  
20 consistently met, we would say, okay.

21 Well, how do we tighten this up a little  
22 bit. Can we be better? Do we need to be better.

23 And if so, what was that metric. One of the things  
24 that we looked at, that we evolved, was training. So  
25 we wanted to make sure all our pharmacists were

1     trained and had the proper training. And we ended up  
2     breaking that down into different segments of  
3     training, so we knew what we were more specific on,  
4     what exactly training are we referring to.

5                 So it was a good process that we had in  
6     place to make sure that we were in good standing  
7     with -- with legal. I guess they're all legal based  
8     -- legal applications.

9                 Q.     And was this a live document that would  
10    live from meeting to meeting and be filled in, you  
11    know, over time?

12                A.     Every quarterly meeting, we had this form  
13    with information that needed to make determinations  
14    of where we are. And the goal was collected for that  
15    meeting. And then we would have records of previous  
16    meetings, like I said, so we could see with -- you  
17    know, what's going on, you know, the board of  
18    pharmacy notices.

19                We were so good, what's happening, where  
20    is this happening? Is it specific -- we would look  
21    into it at that point. That wasn't the case. I'm  
22    giving hypothetical here. We would look into the  
23    situation as, oh, boy, you know, the State of Florida  
24    down in Miami having all these violations. What's  
25    going on. And then depending on the situation, call

1 the supervisor or look at the stores, look at what  
2 the violations were. You know, say, oh, like I said,  
3 the signs might be, oh, we don't have such and such  
4 sign that the State of Florida requires and we would  
5 address that.

6 Q. My question is a little bit different  
7 because I'm just trying to figure out what kind of  
8 documentation is taking place over time for these  
9 pharmacy compliance team meetings. So let's say you  
10 were missing a sign in Miami, and that was a board of  
11 pharmacy notice of violation. Would there be a live  
12 document that the pharmacy compliance team could look  
13 at that, let's say, started on October of 2006, that  
14 said, we had the wrong sign in Miami. And in 2010,  
15 if that issue came up again, you would go back to  
16 some sort of electronic document or matrix that would  
17 tell you, well, back in 2006, we had a problem with  
18 the sign in Miami, and now we have a problem with,  
19 you know, a sign in Sarasota, or something like that,  
20 or was it -- or did you have to go to -- for example,  
21 with the board of pharmacy notice, you had to go to  
22 legal and pharmacy to see what was happening?

23 A. Okay. So using that example and hopefully  
24 this answers your question, there was a sign that was  
25 missing in Miami. The response wouldn't be waiting

1 for this compliance meeting to address the situation.  
2 We would put that -- once we got notification of the  
3 board of pharmacy, which they do inspect pharmacies,  
4 that's their role, to make sure we're compliant with  
5 all the state laws. There's a form that they fill  
6 out. Basically, they check yes or no, basically, if  
7 you're compliant or not, so --

8 Q. I hate to interrupt you, but it's just a  
9 hypothetical. So I understand that you're going to  
10 fix the problem quickly. What I'm trying to  
11 understand is, at the pharmacy compliance team  
12 meeting, if it was 2010, would you have -- would you  
13 be able to tell from this matrix that in 2006 there  
14 was a problem that was solved in Miami?

15 MR. HUDSON: Objection, form.

16 THE WITNESS: I'm trying to answer your  
17 question. The way that phrasing, it wasn't the  
18 modus operandi of our operation for this  
19 process. The purpose of the meeting is to take  
20 a snapshot of our current environment and to see  
21 where we are, look at more recent, you know,  
22 I -- you know, there would be no need for me to  
23 go back four years to say, hey, was this problem  
24 solved.

25 That wasn't the -- the gist of the

1           committee. The committee was to say, hey,  
2           looking at things, do we have an opportunity to  
3           improve? What's our goal? Are we meeting our  
4           goal? If not, how do we -- we address that.

5           Q.       (By Ms. Conroy) Okay. So --

6           A.       I'm sorry, go ahead.

7           Q.       Well, maybe a better way for me to ask it  
8           is, there would be a particular pharmacy metric chart  
9           created for each meeting. And you dealt with those  
10          issues in that chart. And then at the next meeting,  
11          you had another -- had different chart?

12          A.       Yes, every -- every quarter, we would have  
13          fresh data. Now, if there -- like I said, we weren't  
14          blind to the fact that if there was an issue, are we  
15          addressing the issue, are we getting better. So we  
16          looked at more immediate trends. And not from, you  
17          know, back in such and such year, we had a bigger  
18          problem, and so forth.

19                   Then if there were other, like I said, we  
20          had to breakdown different metrics, we would break  
21          those metrics down. Different measures made it  
22          tighter, so we kept on improving.

23          Q.       Okay. Let's take a look on the very first  
24          page, the last paragraph. It says, there were three  
25          investigations reported for the quarter. One

1 I recall the specific meeting about those situations,  
2 but there was -- well, the guy committed suicide,  
3 which is unfortunate.

4 I don't know. That would be really --  
5 these are Karl Zillgitt's notes, and this is what is  
6 of interest. I'm not -- I can't say -- I'm  
7 sure -- well, I could assure you that we address  
8 things as -- as we can, across the way. Why it's not  
9 documented, I would speculate, why that is, or he  
10 just neglected to put it in. And I'm guessing, but  
11 ultimately, we were an improved organization due to  
12 this team.

13 Q. I'm sorry, you were what?

14 A. We were an improved organization. We  
15 learned and we got better.

16 Q. Let's go to the next -- the next one in  
17 the series, which is January 30th of 2007. It's just  
18 one page, I think. And if you look at the very  
19 bottom of the first page, it says, there was one  
20 investigation reported for the quarter. In  
21 responding to a subpoena, it was found that the  
22 physician filled several prescriptions for controlled  
23 substances on the same day, in order to enable the  
24 customer to use manufacturing coupons, which saved  
25 the customer money. Do you see that?

1 just like just industry knowledge that that report  
2 needed, and we wanted to offer.

3 Q. Now, was loss prevention located -- was  
4 that department located in Lakeland?

5 A. Yes, it was.

6 Q. And your department was located in  
7 Lakeland as well, correct?

8 A. That is correct.

9 Q. And is it true that you -- you've  
10 described when you felt it would have been useful for  
11 loss prevention to come and talk to you before they  
12 went and did an investigation. But is it true that  
13 you, as vice president of pharmacy operations, did  
14 not have access to the loss prevention investigation  
15 work ups that they were doing?

16 MR. HUDSON: Objection, form.

17 THE WITNESS: There would be tools that we  
18 had in place that -- in the pharmacy department  
19 that we utilize to look at potential situations  
20 as we saw. And we went through those before  
21 with the several different reports. And not to  
22 mention, supervisors' inspections of the  
23 pharmacy. They were charged with inspecting  
24 each pharmacy annually. Part of that process  
25 was actually going through script by script, C2

1           prescriptions, to make sure they're accurate.

2           Q.       (By Ms. Conroy) But that was your  
3   department, not loss prevention, correct?

4           A.       That is correct.

5           Q.       What I'm talking about is whether your  
6   department had access, open access to the loss  
7   prevention tool that loss prevention used to identify  
8   problems?

9           A.       No, we did not have an opportunity to  
10   manipulate that data. That was all outside -- that's  
11   the fox watching the chicken hen -- chicken house,  
12   rather. So that was all outside of pharmacy that  
13   they would go ahead and have this tool developed by  
14   BAR, to look at or investigate potential theft within  
15   the pharmacy.

16          Q.       And what did you say, developed by what?

17          A.       I'm sorry, that's the Business Analysis  
18   and Reporting.

19          Q.       That's an acronym, Business Analysis --

20          A.       Yeah. BAR is --

21          Q.       Okay. Do you know -- and so at no time  
22   when you were VP of pharmacy operations, did you have  
23   access to the loss prevention or BAR tool?

24          A.       Me personally, no, I did not have access  
25   to that report. And I'm trying to recall for you



1           Q.     So you could -- the data was there, and  
2     you could go in and look more closely at a particular  
3     region or store if you needed to?

4           A.     Yes, ma'am.

5           Q.     Was there ever a concern by you as vice  
6     president of pharmacy operations that the number of  
7     controlled substances that were being dispensed was  
8     increasing over time? Did that ever of cause you any  
9     concern?

10           MR. HUDSON:  Objection, form.

11           THE WITNESS:  I would say that our whole  
12     business increased in our pharmacy.  We did a  
13     great job of growing that business.  And we had  
14     parameters, as I mentioned before, the reporting  
15     that we had in place, especially that -- and you  
16     corrected me before on the name, but that red  
17     line -- red flag report, but that would indicate  
18     if there were issues on a store by store basis.

19           So we would know if there needs to be a  
20     concern, but there was no global increase in C2s  
21     that were outstanding for the whole company, by  
22     percent of controls didn't skyrocket over a  
23     year.  There were stores that had more, stores  
24     that had less, stores that had more that were  
25     outliers, we looked at.

D I S C L O S U R E

STATE OF GEORGIA            )           DEPOSITION OF  
HENRY COUNTY                )           FRED OTTOLINO

Pursuant to Article 10.B of the Rules and Regulations of the Board of Court Reporting of the Judicial Council of Georgia, I make the following disclosure:

I am a Georgia Certified Court Reporter. I am here as a representative of Golkow Technologies.

Golkow Technologies was contacted by the offices of Simmons Hanly Conroy to provide court reporting services for this deposition. Golkow Technologies will not be taking this deposition under any contract that is prohibited by O.C.G.A. 9-11-28 (c).

Golkow Technologies has no contract or agreement to provide court reporting services with any party to the case, or any reporter or reporting agency from whom a referral might have been made to cover the deposition.

Golkow Technologies will charge its usual and customary rates to all parties in the case, and a financial discount will not be given to any party in this litigation.

*F. Renee Finkley*

F. Renee Finkley, RPR, RMR, CRR, CLR  
Georgia CCR-B-2289



To Pharmacy Compliance Team  
From Karl Zillgitt  
Date 10/31/06  
Subject Pharmacy Compliance Team Meeting /3<sup>rd</sup> Quarter 2006

---

#### Introduction

On October 31, 2006, at 12:30 p.m., I met with Fred Ottolino, Jillanne Smith and Steven Resnick for the third quarter, 2006 Pharmacy Compliance Team meeting. The purpose of meeting was to determine the status of Publix's compliance with applicable laws and regulations and to determine whether Publix met its goals under the Pharmacy Metrics during the quarter. A copy of the Metrics is attached along with the 3<sup>rd</sup> quarter results as provided by the Pharmacy Dept. and the Legal Dept.

---

#### Discussion

The first order of discussion was Publix's compliance under the Pharmacy Metrics. Under the first risk, the Team reported that there were no known customer complaints, Board of Pharmacy inquiries or physician complaints of misfills where no QRE was on file. For the second metric, Jillanne provided data from a query run on the sequel server indicating that approximately 1/3 of all pharmacists did not have a level 1 QRE during the prior 12 months. Jillanne reported that the program had to be refined so that new hires and terminating associates during the past 12 months were not included. Due to the lack of historic data regarding this metric, no benchmarks were assigned.

Under the next metric, the % of prescriptions with a QRE, Jillanne provided the attached chart diagramming the metric for the prior 36 months. The trend is still toward a slight increase in the % of prescriptions with a QRE, but the quarter's performance showed a decrease over the prior two quarters.

There were three investigations reported for the quarter. One involved a pharmacist fraudulently billing under another patient's name for entron. This pharmacist will be terminated due to the self serving nature of the activity. Another investigation involved a tech as well as a pharmacist stealing controlled substances, which resulted in both associates being terminated. Finally, a pharmacist created fake vouchers to obtain controlled substances and committed suicide when confronted with the accusation.

*Pharmacy Compliance Team Meeting /3rd Quarter 2006, 10/31/06, 2*

Jillanne reported that the data for HIPAA training and job class training was unreliable and inaccurate. Reporting of job class training would revert to ETD in the near future, so this data was expected to become more reliable. Fred will be proposing a new automated system to allow pharmacists, techs and interns to train online, which automated process records their online training. This is expected to resolve the data accuracy issue.

There was one customer complaint for unauthorized disclosure of PHI. This was a decrease from the prior quarter.

Steve advised that a new classification of Medicare/Medicaid anti-fraud compliance training would have to be implemented for Publix pharmacy associates in the near future. Finally, Steve discussed Publix's challenge of the new South Carolina statute requiring two certified technicians if the ratio of technicians to pharmacists was 3/1. The challenge was submitted administratively to exhaust administrative remedies first.

---

KAZ/jmp



To Pharmacy Compliance Team  
From Karl Zillgitt  
Date 1/30/07  
Subject Pharmacy Compliance Team Meeting /4<sup>th</sup> Quarter 2006

---

#### **Introduction**

On January 30, 2007, at 1:30 p.m., I met with Fred Ottolino and Jillanne Smith for the fourth quarter, 2006 Pharmacy Compliance Team meeting. Steven Resnick and Paul Hines were absent. The purpose of meeting was to determine the status of Publix's compliance with applicable laws and regulations and to determine whether Publix met its goals under the Pharmacy Metrics during the quarter. A copy of the Metrics is attached along with the 4<sup>th</sup> quarter results as provided by the Pharmacy Dept. and the Legal Dept.

---

#### **Discussion**

The first order of discussion was Publix's compliance under the Pharmacy Metrics. Under the first risk, the Team reported that there were no known customer complaints, Board of Pharmacy inquiries or physician complaints of misfills where no QRE was on file. For the second metric, Jillanne provided data from a query run on the sequel server indicating that approximately 1/3 of all pharmacists did not have a level 1 QRE during the prior 12 months. Jillanne reported that the program still had to be tweaked so that new hires and terminating associates during the past 12 months were not included. Because of the technical issues relating to this metric, no benchmarks were assigned.

Under the next metric, the % of prescriptions with a QRE, Jillanne provided the attached chart that shows that the Company performed slightly better than its trend over the prior 36 months. The trend is still toward a slight increase in the % of prescriptions with a QRE, but I confirmed that continued improvement would cause the trend to flatten.

There was one investigation reported for the quarter. In responding to a subpoena, it was found that the physician filled several prescriptions for controlled substances on the same day in order to enable the customer to use manufacturing coupons, which saved the customer money. The physician wrote a prescription for a larger quantity of controlled substances, and the pharmacist

*Pharmacy Compliance Team Meeting /4th Quarter 2006, 1/30/07, 2*

simply treated it as multiple prescriptions in order to take advantage of multiple manufacturing coupons.

Jillanne reported that the data for HIPAA training and job class training continued to be unreliable and inaccurate. Reporting of job class training would revert to ETD in the future, although technology issues were delaying implementation. The Team discussed the proposed automated system to allow pharmacists, techs and interns to train online, which automatically tracked the online training. This would resolve the recordkeeping issue, but the new technology was not expected for some time. The Team discussed where training records would be required to prove training. The new fraud and abuse regulations regarding Medicare part D were one example where training would be required. Under HIPAA, covered entities must train their employees on their policies and procedures related to privacy practices. The Team agreed to discuss the progress Publix made in tracking various training at the next quarterly meeting.

There were two customer complaints for unauthorized disclosure of PHI. This was still within goal. One relates to a pharmacist who pulls out prescription bottle and discusses medication in front of customers at the pharmacy counter. The other involves a pharmacy that left the log book out for other customers to see. The Team discussed whether procedures were in place requiring the pharmacist to direct the patient to the counseling area before discussing the medications in front of other customers. I recommended that such a procedure be adopted if it did not already exist in the R&P Guide.

Jillanne will provide a report for the number of pharmacists with no Level 1 QREs on file for one full year.

---

KAZ/jmp



To Pharmacy Compliance Team  
From Karl Zillgitt  
Date 10/15/07  
Subject Pharmacy Compliance Team Meeting /3<sup>rd</sup> Quarter 2007

---

#### **Introduction**

On October 15<sup>th</sup>, 2007, at 1:30 p.m., I met with Jillanne Smith, Fred Ottolino and Steve Resnick for the 3<sup>rd</sup> quarter, 2007 Pharmacy Compliance Team meeting. Paul Hines was absent. The purpose of meeting was to determine the status of Publix's compliance with applicable laws and regulations and to determine whether Publix met its goals under the Pharmacy Metrics during the quarter. A copy of the Metrics is attached along with the 3<sup>rd</sup> quarter results as provided by the Pharmacy Dept. and the Legal Dept.

---

#### **Discussion**

The first order of discussion was Publix's compliance under the Pharmacy Metrics. Under the first risk, the Team reported that there were no known customer complaints, Board of Pharmacy inquiries or physician complaints of misfills where no QRE was on file. For the second metric, Jillanne provided data from a query run on the sequel server indicating that 768 pharmacists did not have a level 1 QRE during the prior 12 months. The Team discussed how this metric should be used, and decided that the information was good to have as a guide showing whether pharmacists were in general reporting QREs. If the number of pharmacists without a QRE for the quarter increased sharply, the Team would know that QREs were not being reported.

As to the % of prescriptions with a QRE, Jillanne provided the attached chart that shows that the Company had an overall decline in this metric. The quarter's performance was the first quarter that the Company's trend reversed direction and showed a slight decrease in the % of prescriptions with a QRE.

There were no governmental agency violations for filing a false claim. There were no suspicious purchases/activities made by a pharmacist for the quarter. Fred asked if we could include suspicious purchases identified by Loss Prevention. Fred advised that Loss Prevention had a tool allowing the department to identify from time to time the controlled substance purchasing activities of one or more pharmacies and compare it to that pharmacy's sales. I agreed to ask Loss Prevention if it could provide the Team with the number of

*Pharmacy Compliance Team Meeting /3rd Quarter 2007, 10/15/07, 2*

suspicious pharmacy purchases occurring at Publix pharmacies for each quarter, but also informed the Team that Loss Prevention may not want to provide this information to the Team. There were no investigations regarding pharmacies or pharmacists reported for the quarter.

There were two customer complaints for unauthorized disclosure of PHI. This was still within goal. No governmental agency investigations existed at present, and no governmental agency notices of violation for unauthorized disclosure of PHI were received by Publix.

Jillanne reported that the data for HIPAA training and job class training continued to be unreliable and inaccurate, but it was the best information available. As in past quarters, ETD has failed to report the number of associate's who had completed job class training. Jillanne advised that ETD was working on this problem and should have a resolution shortly.

The Team discussed the proposed computer based training (CBT) to allow pharmacists, techs and interns to train online. Pharmacy will be providing some of its courses via CBT, including job class training, meth training and HIPAA training. However, the IS solution for tracking the training was not given a high priority. Without a better tracking mechanism, training will continue to be reported by the AC's, and remain inaccurate. Fred asked that the benchmarks for the metrics regarding HIPAA training be changed to a goal of 0, since the regulations clearly provide for training prior to any associate's commencing employment. The Team agreed to change the benchmarks for this metric, and I agreed to inform John Attaway of the issue again.

The Team also discussed adding a metric for meth training, as the new federal regulations require Publix to certify as to the training of all associates handling meth transactions. The Team agreed to add a new metric under "Failure to train associates", tracking the number of associates that haven't completed meth training as of the date the certification is signed. This metric will only be reviewed during quarters when the certification is signed. The Team also established benchmarks for this metric: of a goal of 0, as the certification requirement does not allow any room for error.

---

KAZ/jmp





To Pharmacy Compliance Team  
From Karl Zillgitt  
Date 2/4/08  
Subject Pharmacy Compliance Team Meeting /4<sup>th</sup> Quarter 2007

---

#### **Introduction**

On February 4<sup>th</sup>, 2008, at 1:00 p.m., I met with Jillanne Smith, Paul Hines, and Samantha Tiwari for the 4<sup>th</sup> quarter, 2007 Pharmacy Compliance Team meeting. Steve Resnick was absent. The purpose of meeting was to determine the status of Publix's compliance with applicable laws and regulations and to determine whether Publix met its goals under the Pharmacy Metrics during the quarter. A copy of the Metrics is attached along with the 4<sup>th</sup> quarter results as provided by the Pharmacy Dept. and the Legal Dept.

---

#### **Discussion**

The first order of discussion was Publix's compliance under the Pharmacy Metrics. Under the first risk, the Team reported that there were no known customer complaints, Board of Pharmacy inquiries or physician complaints of misfills where no QRE was on file. For the second metric, Jillanne provided data showing that 778 pharmacists did not have a level 1 QRE during the prior 12 months. The Team discussed whether this metric should be continued, and decided that the information was good to have as a guide showing over time how many pharmacists did not report a QREs. If the number of pharmacists without a QRE for the quarter increased sharply, the Team would know that QREs were not being reported.

As to the % of prescriptions with a QRE, Jillanne provided the attached chart that shows that the Company had a slight increase in the % of prescriptions with a QRE. However, the Company's trend continued in the direction of a slight decrease in the % of prescriptions with a QRE.

There were no governmental agency violations for filing a false claim. There were no suspicious purchases/activities made by a pharmacist for the quarter. I forwarded an email to Dennis Wamsley on 10/15/07 requesting information on suspicious controlled substance purchasing activities at Publix pharmacies, and Dennis agreed to provide certain information regarding suspicious pharmacy purchases for each quarter. There were a few ongoing investigations regarding pharmacies or pharmacists reported by Loss Prevention.

*Pharmacy Compliance Team Meeting /4th Quarter 2007, 2/4/08, 2*

There were three customer complaints for unauthorized disclosure of PHI. This was a moderate hazard, but there is HIPAA policy in place and associates continue to receive training on HIPAA. No governmental agency investigations existed at present, and no governmental agency notices of violation for unauthorized disclosure of PHI were received by Publix.

Jillanne reported that the data for HIPAA training was more reliable this time. However, ETD still failed to report the number of associate's who have completed job class training.

The Team then discussed the annual risk assessment and the Pharmacy Risk Assessment Matrix. Attached is the Matrix that was completed at the meeting, with all of the hazards assessed for severity and probability. A few additional hazards were identified through discussions with the Team. After analyzing all of the hazards, the Team decided to retain the current Metrics, but to add the following new metrics. The failure to maintain patient profiles and prescription files will be determined from a self-audit process developed by Samantha.

		<b>Metric</b>	<b>Benchmark</b>		<b>Owner</b>	<b>Qtr. Resu</b>
Failure to maintain patient profiles and prescription files		# of pharmacies with duplicate patient profiles and/or prescription files	Goal: _____ Moderate hazard: _____ Severe hazard: _____	Pharmacy Self-Audit Report	Pharm.	
		# of Board of Pharmacy Notices of Violation	Goal: _____ Moderate hazard: _____ Severe hazard: _____	Notice of Gov't Agency violation	Legal and Pharm.	
Failure to prevent counterfeit product or product tampering		# of customer complaints regarding counterfeit product or product tampering	Goal: _____ Moderate hazard: _____ Severe hazard: _____	QRE Tracking Report	Pharm.	

---

KAZ/jmp



To Pharmacy Compliance Team  
From Karl Zillgitt  
Date 4/15/08  
Subject Pharmacy Compliance Team Meeting /1<sup>st</sup> Quarter 2008

---

#### **Introduction**

On July 15<sup>th</sup>, 2008, at 1:00 p.m., I met with Samantha Tiwari, Steve Resnick and Fred Ottolino for the 2<sup>nd</sup> quarter, 2008 Pharmacy Compliance Team meeting. The purpose of meeting was to determine the status of Publix's compliance with applicable laws and regulations and to determine whether Publix met its goals under the Pharmacy Metrics during the quarter. A copy of the Metrics is attached along with the 2<sup>nd</sup> quarter results as provided by the Pharmacy Dept. and the Legal Dept.

---

#### **Discussion**

The first order of discussion was to determine Publix's compliance under the Pharmacy Metrics. Under the first risk, the Team reported that there were no customer complaints of a misfill where no corresponding QRE was on file. For the second metric, Samantha provided data showing that 753 pharmacists did not have a level 1 QRE during the prior 12 months. This was consistent with the performance of the Company in prior quarters.

As to the % of prescriptions with a QRE, Samantha provided the attached chart showing that the Company remained the stagnant in the % of prescriptions with a QRE, and the Company's trend continued in the direction of a slight decrease in the % of prescriptions with a QRE.

There were no governmental agency violations for filing a false claim. The Team discussed whether a metric to monitor false claims activity was warranted given the increased level of Medicare/Medicaid enforcement proceedings. Steve asked if pre or post billing audits could be conducted at pharmacies randomly, comparing billing information with prescription files. Fred disliked the idea, but advised that Mary Vickers currently pulled samples of scripts and compared them to prescription files to see if they were legitimate. Mary would determine if the Medicaid/Medicare scripts were tamper proof, which is a requirement for all Medicaid/Medicare scripts. The Team agreed that at the next quarterly meeting, Pharmacy would report on the number of Medicaid/Medicare scripts were not tamper proof or otherwise legitimate.

*Pharmacy Compliance Team Meeting /1st Quarter 2008, 4/15/08, 2*

There was little data regarding suspicious purchases made by Publix pharmacies compared with sales since the Controlled Substance Variance Report was not operating in BAR yet. I reported that Dennis Wamsley had approved review of the LP Analyzer information by Chris in the Pharmacy Dept. I also reviewed information provided by Loss Prevention on suspicious or fraudulent controlled substance purchasing activities at Publix pharmacies. This report showed suspicious purchasing activity at several Publix Pharmacies.

There were two customer complaints for unauthorized disclosure of PHI. This was within goal. No governmental agency investigations existed at present, and no governmental agency notices of violation for unauthorized disclosure of PHI were received by Publix.

Samantha reported that the data for HIPAA training was still just an estimate and ETD still cannot report the number of associate's who have completed job class training. There still were no self audits being conducted randomly at Pharmacies. There were no government agency notices of violations for a failure to maintain patient profiles and prescription files. Finally, there were no reported customer complaints regarding counterfeit product or product tampering.

---

KAZ/jmp



To Pharmacy Compliance Team  
From Karl Zillgitt  
Date 4/15/08  
Subject Pharmacy Compliance Team Meeting /1<sup>st</sup> Quarter 2008

---

#### **Introduction**

On April 15<sup>th</sup>, 2008, at 1:00 p.m., I met with Jillanne Smith, Paul Hines, Samantha Tiwari, Steve Resnick and Fred Ottolino for the 1<sup>st</sup> quarter, 2008 Pharmacy Compliance Team meeting. The purpose of meeting was to determine the status of Publix's compliance with applicable laws and regulations and to determine whether Publix met its goals under the Pharmacy Metrics during the quarter. A copy of the Metrics is attached along with the 1<sup>st</sup> quarter results as provided by the Pharmacy Dept. and the Legal Dept.

---

#### **Discussion**

The first order of discussion of the new metrics added as a result of the risk assessment performed at the last quarterly compliance team meeting. Fred inquired as to how the new metric regarding tampering or counterfeit issues regarding drugs dispensed by Publix would improve compliance. I advised that we were monitoring this risk because it was determined to be a moderate risk during the risk assessment, due to the fact that a failure could have critical consequences or damage to Publix's reputation. The metric would only be measured, and no corrective action was being taken yet.

The next matter was to determine Publix's compliance under the Pharmacy Metrics. Under the first risk, the Team reported that there was one possible customer complaint of a misfill where no corresponding QRE was on file for at least a week. For the second metric, Jillanne provided data showing that 758 pharmacists did not have a level 1 QRE during the prior 12 months. The Team agreed to continue to watch this metric.

As to the % of prescriptions with a QRE, Jillanne provided the attached chart that shows that the Company had a decrease in the % of prescriptions with a QRE, and the Company's trend continued in the direction of a slight decrease in the % of prescriptions with a QRE.

There were no governmental agency violations for filing a false claim. There was no data for the number of suspicious purchases/activities made by a

*Pharmacy Compliance Team Meeting /1st Quarter 2008, 4/15/08, 2*

pharmacist for the quarter, as the Controlled Substance Variance Report was not operating in BAR for the entire quarter. I reported that Dennis Wamsley was now providing information on suspicious or fraudulent controlled substance purchasing activities at Publix pharmacies, but I had not received the report for the 1<sup>st</sup> quarter of 2008.

There were two customer complaints for unauthorized disclosure of PHI. This was within goal. No governmental agency investigations existed at present, and no governmental agency notices of violation for unauthorized disclosure of PHI were received by Publix.

Jillanne reported that the data for HIPAA training was still just an estimate and ETD still cannot report the number of associate's who have completed job class training. Finally, Jillanne reported that she did receive data for job class training tracking, but she had to verify the data because the number of employees receiving the job class training appeared too low.

---

KAZ/jmp



To Pharmacy Compliance Team  
From Karl Zillgitt  
Date 2/17/09  
Subject Pharmacy Compliance Team Meeting /4<sup>th</sup> Quarter 2008

---

#### **Introduction**

On February 17<sup>th</sup>, 2009, at 9:00 a.m., I met with Jillanne Smith, Paul Hines, Samantha Tiwari and Steve Resnick for the 4<sup>th</sup> quarter, 2008 Pharmacy Compliance Team meeting. The purpose of meeting was to determine the status of Publix's compliance with applicable laws and regulations, to determine whether Publix met its goals under the Pharmacy Metrics during the quarter and to conduct a Risk Assessment to determine the risks applicable to the business and whether Publix was adequately monitoring those risks. A copy of the Metrics is attached along with the 4<sup>th</sup> quarter results as provided by the Pharmacy Dept. and the Legal Dept.

---

#### **Discussion**

The first order of discussion was Publix's compliance under the Pharmacy Metrics. Under the first risk, the Team reported that there were no known customer complaints, Board of Pharmacy inquiries or physician complaints of misfills where no QRE was on file. The Team decided to remove the words "for pharmacies" from the metric, as the metric related to misfills filled by pharmacists. It was uncertain as to who was monitoring customer complaints for dispensing errors and misfills, but the Team decided that all complaints of a misfill provided to Samantha will be reported by Pharmacy.

For the second metric, Jillanne provided data showing that 866 pharmacists did not have a level 1 QRE during the prior 12 months. The Team decided that the information was useful and would continue to monitor this information.

As to the % of prescriptions with a QRE, Samantha provided the attached chart that shows that the % of prescriptions with a QRE continued its downward trend.

There were no governmental agency violations for filing a false claim. There were no suspicious purchases/activities made by a pharmacist for the quarter. The Team decided to change this metric to "# of cases of associate embezzlement" as the LP Report provided over the past three quarters reported only on employee embezzlements of narcotics and other valuable drugs. Legal

*Pharmacy Compliance Team Meeting /4th Quarter 2008, 2/17/09, 2*

would report on this metric, but Fred advised that he would talk with Dennis to see if Pharmacy could obtain a trends report so that it could be proactive in preventing associate embezzlement.

There were no customer complaints for unauthorized disclosure of PHI. No governmental agency investigations existed at present, and no governmental agency notices of violation for unauthorized disclosure of PHI were received by Publix.

The Team changed the metric regarding the # of customer HIPAA complaints for unauthorized disclosure of PHI to the # of legitimate customer HIPAA complaints for unauthorized disclosure of PHI, as many of the complaints were not legitimate and should not be reported on. The Team discussed the training, and it was determined that compliance training would soon be able to be reported separately, which would make the training metric more effective.

The Team discussed the new metric for Failure to prevent counterfeit product or product tampering. Finding that this was still a valid risk, the metric was changed to # of known incidents of counterfeit product or product tampering, as not all incidents were reported to Pharmacy.

The Team then discussed the annual risk assessment and the Pharmacy Risk Assessment Matrix. Attached is the Matrix that was completed at the meeting, with all of the hazards assessed for severity and probability. A few additional hazards were identified through discussions with the Team. After analyzing all of the hazards, the Team decided to retain the current Metrics, as revised above. The Team discussed Ga. Code section 26-4-12, which required the reporting of missing drugs and significant adverse drug reactions to the Board of Pharmacy. It was determined that Publix may or may not be report missing drugs o the Board. Steve agreed to further investigate. A new hazard, failure to properly document prescriptions for C-III through C-V in Florida was raised.

---

KAZ/jmp





To Pharmacy Compliance Team  
From Karl Zillgitt  
Date 10/15/10  
Subject Pharmacy Compliance Team Meeting /3<sup>rd</sup> Quarter 2010

---

#### **Introduction**

On October 15<sup>th</sup>, 2010, at 1:00 p.m., I met with , Fred Ottolino, Samantha Tiwari and Steve Resnick for the 3<sup>rd</sup> quarter, 2010 Pharmacy Compliance Team meeting. The purpose of meeting was to determine the status of Publix's compliance with applicable laws and regulations and to determine whether Publix met its goals under the Pharmacy Metrics during the quarter. Copies of the Metrics and the 3<sup>rd</sup> quarter results provided by the Pharmacy Dept. and the Legal Dept. are attached.

---

#### **Discussion**

The first order of discussion was Publix's compliance under the Pharmacy Metrics. Under the first risk, the Team reported 1 known Board of Pharmacy inquiry of a misfill where no corresponding QRE was on file. The Team discussed the missing QRE report in the Risk Management database from the last quarter, and Samantha advised that there was a retail QRE report filed in that case, so it was a false alarm. Melynda Heidle is following up with the Board of Pharmacy on the present case.

For the second metric, there were 947 pharmacists that did not have a level 1 QRE during the prior 12 months, or 48.36% of the pharmacists. Samantha did not provide the QRE trend chart because Risk Management was not inputting the QRE data fast enough. At one time, QRE data was input daily so that QRE counseling reports could be pulled for review with the pharmacist in a timely manner. Risk Management fell behind in inputting the data so QRE Counseling Reports had to be pulled weekly. Today, it is taking Risk Management 3-5 weeks to input the data, so by the time the Pharmacy supervisors and Pharmacy operations managers obtain the report and review the QRE with the pharmacist, knowledge of the event has passed. This is making the QRE process ineffective.

There were no governmental agency violations for filing a false claim. There were 4 known episodes of pharmacy associates embezzling prescription drugs, as reported via the LP Analyzer. The Team discussed pharmacists' misuse of the system in order achieve greater compensation. Apparently, physicians were receiving compensation incentives if refill prescriptions came through via the

*Pharmacy Compliance Team Meeting /3rd Quarter 2010, 10/15/10, 2*

automated system (IVR). Pharmacists were receiving calls from customers asking for refills for their prescriptions, but the pharmacists were inputting these through the IVR system to make them appear as if they were refilled through the automated reminder process. Pharmacists also may receive incentive compensation if they sell a specified number of prescriptions per hour. Some pharmacists were sending phony sales of prescriptions through the system at \$0 in order to increase sales data and compensation. Some pharmacists have been terminated for manipulating the system in this manner.

There were no known Government agency investigations regarding Publix pharmacies or pharmacists and controlled substances.

There were 2 HIPAA customer complaints for unauthorized disclosure of PHI. One customer alleged that the Pharmacy technician, the customer's ex-wife, accessed the customer's prescription profile. In another case, the customer alleged that the Pharmacy associate accessed her prescription profile information and emailed it from the associate's personal computer. The Pharmacy district manager investigated these complaints.

As to training, it was determined that 85 out of 4,245 associates had not completed HIPAA Privacy and Security training within 2 weeks of hire, or 2.0%. This was a substantial increase from the last quarter, but a new process for counting the new hires who had not been trained within the first two weeks of hire was implemented. Fred suggested implementing a corrective action of locking out associates from clocking in if they do not have the HIPAA training logged into the system within the first 2 weeks of hire. Fred would discuss this with Tracy and report at the next quarterly meeting.

As to the # of stores with poor internal review/inspection reports, Pharmacy did not receive any poor state inspection reports. Pharmacy had 134 Pharmacy technicians and interns out of 2,287, or 5.85%, who did not have job class training within 120 days of hire. Fred asked that this Metric be changed to the # and % of Pharmacy Technicians and Interns who haven't completed JCT within 180 days of hire, because the law required technician training to be completed within 180 days, and technician training was being rolled into JCT. 49 out of 4,242 Pharmacy associates haven't completed initial or annual fraud and abuse training, or 1.15%.

As to the # of patients identified in the Pharmacy records with suspected duplicate patient profiles, there were 92,875 patients with suspected duplicate patient profiles as of the end of September, 2010. This was an increase from the last quarter, but Fred explained that these duplicate patient profiles were being identified because Publix was transitioning to the new Pharmacy RX system.

As to the failure to prevent counterfeit product or product tampering, there were no known incidents of counterfeit product or product tampering. In a random sampling taken in the 3<sup>rd</sup> quarter of 2010, out of a sample of 400 Medicaid prescriptions filled during the 3<sup>rd</sup> quarter, 2010, only 6 or 1.5% were not written on tamper resistant prescription pads. This was a significant decrease from the last two quarters. Under the Medicaid rules, in order for outpatient drugs to be reimbursable by Medicaid, all written, non-electronic prescriptions must be executed on tamper-resistant pads.

*Pharmacy Compliance Team Meeting /3rd Quarter 2010, 10/15/10, 3*

---

KAZ/jmp



To Pharmacy Compliance Team  
From Karl Zillgitt  
Date 1/18/11  
Subject Pharmacy Compliance Team Meeting /4<sup>th</sup> Quarter 2010

---

#### **Introduction**

On January 18<sup>th</sup>, 2011, at 1:30 p.m., I met with , Fred Ottolino, Samantha Tiwari, Jillanne Smith and Steve Resnick for the 4<sup>rd</sup> quarter, 2010 Pharmacy Compliance Team meeting. The purpose of meeting was to determine the status of Publix's compliance with applicable laws and regulations and to determine whether Publix met its goals under the Pharmacy Metrics during the quarter. The Team also conducted a Risk Assessment and completed a Risk Assessment Matrix listing the hazards the company faced and assessing the risk associated with those hazards. Copies of the Metrics for the 4<sup>th</sup> quarter and Risk Assessment Matrix are attached.

---

#### **Discussion**

The first order of discussion was Publix's compliance under the Pharmacy Metrics. Under the first risk, the Team reported 0 known Customer Complaint, Board of Pharmacy inquiry or physician complaint of a misfill where no corresponding QRE was on file.

For the second metric, there were 826 pharmacists that did not have a level 1 QRE during the prior 12 months, or 42.34% of the pharmacists. Samantha provided the QRE trend chart which showed a downward trend in the number of level 1 QREs per pharmacist during the last 12 months.

There were no governmental agency violations for filing a false claim. There was 1 known episode of a pharmacy associate embezzling prescription drugs, as reported via the LP Analyzer. The Team discussed pharmacists' misuse of the system in order to achieve greater compensation. There was another incident of a pharmacist receiving compensation incentives by refill prescriptions via the automated system (IVR). The pharmacist received a call from customers asking for refills for their prescriptions, but the pharmacist input these through the IVR system (through publix.com) to make them appear as if they were refilled through the automated reminder process. The pharmacists involved have been terminated. The Team also discussed the fact that Georgia Dept. of Drugs & Narcotics were interviewing associates at the same time that LP interviewed the

*Pharmacy Compliance Team Meeting /4th Quarter 2010, 1/18/11, 2*

associates. Steve Resnick advised that he would speak with Dennis Wamsley to make sure that Legal was involved when the State agents requested interviews with associates.

There were no known Government agency investigations regarding Publix pharmacies or pharmacists and controlled substances.

There were 5 HIPAA customer complaints for unauthorized disclosure of PHI. One customer alleged that the Pharmacist shouted the customer's PHI in front of other customers. The other incidents involved prescription information or receipts being given to the wrong patient via a bag mix-up. The Pharmacy district managers investigated these complaints. There were no governmental agency notices of violation for unauthorized disclosure of PHI.

As to training, it was determined that 109 out of 4,322 associates had not completed HIPAA Privacy and Security training within 2 weeks of hire, or 2.56%. This was a substantial increase from the last quarter. Fred talked with Tracy about implementing a corrective action plan of locking out associates from clocking in if they do not have the HIPAA training logged into the system within the first 2 weeks of hire. Fred advised that such a process could not be implemented feasibly. Supervisors are tracking down associates that do not have the training to make sure they have the training, or the training is properly documented in the system. There will be a new management system in place by Q1 of 2012 that will track the training completion of CBT electronically.

As to the # of stores with poor internal review/inspection reports, Pharmacy did not receive any poor state inspection reports for the quarter. Pharmacy had 110 Pharmacy technicians and interns out of 2,371, or 4.64%, who did not have job class training within 120 days of hire. Fred asked that this Metric be changed to correlate with the new Florida requirement for pharmacy technician training completed within 180 days of hire. The Team agreed to change the metric to the following:

the # and % of Florida Pharmacy Technicians who haven't completed JCT within 180 days of hire

26 out of 4,322 Pharmacy associates haven't completed initial or annual fraud and abuse training, or 0.60%. This was a vast improvement from the last quarter.

As to the # of patients identified in the Pharmacy records with suspected duplicate patient profiles, there was no data yet for the metric. Fred asked that this metric be removed since it was not based upon any legal requirement, just business risk. The Team agreed to remove both the metric regarding the number of patients with suspected duplicate patient profiles and the number of Board of Pharmacy Notices of Violation for failure to maintain patient profiles and prescription files.

As to the failure to prevent counterfeit product or product tampering, there were no known incidents of counterfeit product or product tampering. In a random sampling taken in the 4<sup>th</sup> quarter of 2010, out of a sample of 360 Medicaid prescriptions filled during the 4<sup>th</sup> quarter, 2010, only 9 or 2.5% were not written on tamper resistant prescription pads. Under the Medicaid rules, in order for outpatient drugs to be reimbursable by Medicaid, all written, non-electronic prescriptions must be executed on tamper-resistant pads.

*Pharmacy Compliance Team Meeting /4th Quarter 2010, 1/18/11, 3*

The Team then discussed the annual risk assessment and the Pharmacy Risk Assessment Matrix. The attached Matrix was completed at the meeting, with all of the hazards assessed for severity and probability. The Team identified three new hazards, one relating to fraud and abuse annual renewal training, one regarding combat meth training upon hire and Medicaid prescriptions filled without tamper resistant scripts. After analyzing all of the hazards, the Team decided that in addition to the changes to the Metrics recommended by Fred, an additional Metric would be added under "Failure to Train New Associates with Methguard CBT", which would read as follows:

# and % of new Pharmacy associates that haven't completed Methguard CBT within 2 weeks of hire.

No benchmarks were established for this metric. In addition, the Team discussed the other metrics where no benchmarks had been established and decided to discuss benchmarks at the next meeting.

---

KAZ/jmp



To Pharmacy Compliance Team  
From Karl Zillgitt  
Date 4/13/12  
Subject Pharmacy Compliance Team Meeting 1<sup>st</sup> Quarter 2012

---

#### **Introduction**

On Friday, April 13<sup>th</sup>, 2012, at 9:00 a.m., I met with , Fred Ottolino, Erin Avella, Jillanne Smith and Steve Resnick for the 1<sup>st</sup> quarter, 2012 Pharmacy Compliance Team meeting. The purpose of meeting was to determine the status of Publix's compliance with applicable laws and regulations A copy of the Metrics for the 1<sup>st</sup> quarter is attached.

---

#### **Discussion**

The first order of discussion was Publix's compliance under the Pharmacy Metrics. Under the first risk, the Team reported 0 known Customer Complaints, Board of Pharmacy inquiries or physician complaints of a misfill where no corresponding QRE was on file.

For the second metric, the percentage of prescriptions with a QRE was still at about .01%, and the trend remained pointed upward.

There were no governmental agency violations for filing a false claim. There were 3 known episodes of a pharmacy associate embezzling prescription drugs. There were no known Government agency investigations regarding Publix pharmacies or pharmacists and controlled substances. For the number of times a pharmacy requested at least two increases during the quarter of the pharmacy's controlled substance purchasing allocation as set by McKessen, there was one store that had made two increases during the quarter. Fred asked to review the report with respect to that store and noted that several major pharmacies were being tagged for issuing too many controlled substances to single customers, and that Publix would be on the radar screen for similar activity.

There were 2 HIPAA customer complaints for unauthorized disclosure of PHI. First, there was an OCR investigation regarding an alleged grocery manager who was given access to a customer's prescriptions. The pharmacist was counseled. Second, there was an OCR investigation regarding an allegation of a Pharmacy Tech disclosing PHI by shouting the medication name loudly in front of other customers. The OCR investigation is ongoing, but Publix has determined that

*Pharmacy Compliance Team Meeting 1st Quarter 2012, 4/13/12, 2*

there is no validity to the complaint. An incident occurred at a Lakeland division pharmacy that was determined to not involve a privacy issue:

A customer dropped off 6 prescriptions for her husband, daughter and herself and told the pharmacy technician she will be back later to pick them up. The pharmacy filled the prescriptions and placed them in the pickup bins. The pharmacy received a call allegedly from the customer's daughter to see if her prescriptions were ready for pickup. She also asked if her parent's prescriptions were also ready. The technician told the daughter that her prescriptions were ready but could not give any information about her parent's prescriptions. The daughter arrived at the pharmacy, the technician verified the patient by asking the patient for her current home address, the patient signed for the prescriptions and left the store. About an hour after the medication was picked up, the husband of the customer's daughter arrived at the pharmacy to pick up his wife's prescriptions. The technician told him that his wife already picked them up. He said she never left home and someone else picked them up. The customer and her husband also arrived at the pharmacy, they were told of the situation. Upon review of the video tape of the person picking up the medication, the customer, her husband and the son-in-law all claimed they could not identify the person in the tape picking up the medication. A police report was filed describing the incident. The pharmacist called the daughter's physician and explained the situation and asked for the prescription to be re-written. The physician looked into his patient records and denied ever refilling the prescriptions.

As to training, 4 out of 291 associates had not completed HIPAA Privacy and Security training within 2 weeks of hire, or 1.37%. The denominator of this metric was limited to Pharmacy associates hired within the quarter. This was a substantial improvement from the last quarter. There was one government agency violation for unauthorized disclosure of PHI, the first HIPAA complaint noted above, which the OCR determined was a valid complaint. Publix is expecting a fine for this violation.

There were no pharmacies with a complaint filed against them by a State agency where probable cause was found.

As to the number of Pharmacy technicians who did not have job class training within 180 days of hire, 24 out of 129 or 18.6% did not have job class training. This was substantial improvement from the last quarter.

There were 3 out of 4,287 Pharmacy associates that had not completed annual renewal fraud and abuse training, or 0.7%. There were 2 out of 291 associates that had not completed Fraud, Waste and Abuse training within 2 weeks of hire. This was substantial improvement from the last quarter.

In a random sampling taken in the 1<sup>st</sup> quarter of 2012, out of a sample of 156 Medicaid prescriptions filled during the quarter, only 1 or 0.64% were not written on tamper resistant prescription pads.

Finally, 5 out of 291 associates, or 1.72% of new Pharmacy associates had not completed Combat Meth training within 2 weeks of hire. This was substantial improvement from the last quarter.



*Pharmacy Compliance Team Meeting 1st Quarter 2012, 4/13/12, 3*

---

KAZ/



To Pharmacy Compliance Team  
From Karl Zillgitt  
Date 1/22/13  
Subject Pharmacy Compliance Team Meeting 4<sup>th</sup> Quarter 2012

---

#### **Introduction**

On Tuesday, January 22, 2013, at 2:00 p.m., I met with Fred Ottolino, Erin Avella and Jillanne Smith for the 4<sup>th</sup> quarter, 2012 Pharmacy Compliance Team meeting. The purpose of the meeting was to determine the status of Publix's compliance with applicable laws and regulations. The Team also conducted a Risk Assessment and completed a Risk Assessment Matrix listing the hazards the company faced and assessing the risk associated with those hazards. A copy of the Metrics for the 4<sup>th</sup> quarter and the Risk Assessment are attached.

---

#### **Discussion**

The first order of discussion was Publix's compliance under the Pharmacy Metrics. Under the first risk, the Team reported 0 known Customer Complaints, Board of Pharmacy inquiries or physician complaints of a misfill where no corresponding QRE was on file.

For the second metric, the percentage of prescriptions with a QRE was .013%, a slight decrease from the last quarter. Erin provided a copy of the trending chart, which is now pointing slightly downward.

There were no governmental agency violations for filing a false claim. There were 4 known episodes of a pharmacy associate embezzling prescription drugs. One of the instances involved a pharmacy manager who embezzled \$50,000+ of controlled substances and sold the substances to strippers and a nearby strip club. Fred advised that the Rx Pharmacy Management system had all of the controls possible, but that pharmacists were still able to fabricate prescriptions and embezzle drugs. There was one known Government agency investigation relating to the pharmacy manager just described. For the number of times a pharmacy requested at least two increases during the quarter of the pharmacy's controlled substance purchasing allocation as set by McKessen, no store had requested two increases during the quarter.

There was 1 HIPAA customer complaint for unauthorized disclosure of PHI. The complaint involved a pharmacy loudly stating PHI in front of other customers.

*Pharmacy Compliance Team Meeting 4th Quarter 2012, 1/22/13, 2*

As to training, 6 out 251 associates had not completed HIPAA Privacy and Security training within 2 weeks of hire, or 2.40%, within goal. There were no government agency violations for unauthorized disclosure of PHI.

There were no pharmacies with a complaint filed against them by a State agency where probable cause was found.

As to the number of Pharmacy technicians who did not have job class training within 180 days of hire, 15 out of 108 or 13.89% did not have job class training. This was an increase from the last quarter, and puts Publix in the severe hazard category. The new LRS was now in place so records of training did not have to be input by the AC. The next quarterly report should have a significant decrease in the number of Pharmacy technicians who do not have JCT within 180 days of hire, as Pharmacy has a policy in place of not allowing new Pharmacy technicians to work without the training. There were 8 out of 5,263 Pharmacy associates that had not completed annual renewal fraud and abuse training, or 0.15%, within goal. There were 4 out of 251 associates that had not completed Fraud, Waste and Abuse training within 2 weeks of hire, or 1.60%, within goal.

In a random sampling taken in the 4<sup>th</sup> quarter of 2012, out of a sample of 152 Medicaid prescriptions filled during the quarter, none were found not written on tamper resistant prescription pads, within goal.

Finally, 5 out of 251 associates, or 2.0% of new Pharmacy associates had not completed Combat Meth training within 2 weeks of hire, within goal.

The Team then discussed the annual risk assessment and the Pharmacy Risk Assessment Matrix. The attached Matrix was completed at the meeting, with all of the hazards assessed for severity and probability. The Team identified one new hazard, improper dispensing of controlled substances, referring to multiple prescriptions being filled for controlled substances prescribed by multiple physicians to one customer. All of the risks were determined to be low, based upon controls currently in place, so no new metrics were added.

The Team discussed the metrics where no benchmarks had been established and decided to implement the following benchmarks:.

Failure to control loss or theft of controlled substances and other pharmaceuticals	# of times a pharmacy requested at least two increases during the quarter of the pharmacy's controlled substance purchasing allocation as set by McKessen	Goal: 0	McKessen Controlled Substance Report	Pharm
Failure to train associates	# of associates that haven't completed Fraud, Waste & Abuse renewal training	Goal: <.5% Mod. H.: .5-2% Sev. H.: >2%	Training Tracking Report	Pharm

KAZ/

*Pharmacy Compliance Team Meeting 4th Quarter 2012, 1/22/13, 3*



To Pharmacy Compliance Team  
From Karl Zillgitt  
Date 2/19/15  
Subject Pharmacy Compliance Team Meeting 4<sup>th</sup> Quarter 2014

---

#### **Introduction**

On Thursday, February 19, 2015, at 9:30 a.m., I met with Andy Shaw, Jillanne Smith, Ashley Greathouse and Jonn Hoppe for the 4<sup>th</sup> quarter, 2014 Pharmacy Compliance Team meeting. The purpose of the meeting was to determine the status of Publix's compliance with applicable laws and regulations. The Team also conducted a Risk Assessment and completed a Risk Assessment Matrix listing the hazards the company faced and assessing the risk associated with those hazards. A copy of the Metrics for the 4<sup>th</sup> quarter and the Risk Assessment are attached.

---

#### **Discussion**

The first order of discussion was Publix's compliance under the Pharmacy Metrics. Under the first risk, the Team reported 0 known Customer Complaints, Board of Pharmacy inquiries or physician complaints of a misfill where no corresponding QRE was on file.

For the second metric, the percentage of prescriptions with a QRE was .012%, a decrease from the last quarter. Jillanne provided a copy of the trending chart, which continues to point downward.

There were no governmental agency violations for filing a false claim. There were two known episodes of a pharmacy associate embezzling prescription drugs from the RX Analyzer Report. I asked the Team if any procedures had been implemented to make it more difficult to maintain the confidentiality of the Pharmacy manager's override key so that refunds could not be processed by clerks or Techs to the associate's own debit/credit cards. Jillanne advised that this issue existed throughout Customer Service as well, and that Pharmacy had stricter procedures in place to maintain the confidentiality of the override key than in other depts.

There was one Government agency investigation regarding Publix pharmacies and the loss of controlled substances. A Dept. of Health inspector interviewed a Pharmacy manager and concluded that Publix did not have controls in place to

*Pharmacy Compliance Team Meeting 4th Quarter 2014, 2/19/15, 2*

adequately monitor controlled substance inventory. It was determined that there was a computer glitch caused by the conversion of the systems to Pharmacy Rx, which has subsequently been addressed. The investigation has been closed without any action being taken. For the number of times a pharmacy requested at least two increases during the quarter of the pharmacy's controlled substance purchasing allocation as set by McKesson, no stores had requested two increases during the quarter.

There were 2 legitimate HIPAA customer complaint for unauthorized disclosure of PHI, within goal. On 11/21/2014, at Pharmacy 0023, patient alleges the Pharmacy called out her medication, which was a narcotic, and refused to fill it. It was actually too early to obtain a refill and the prescription was not a narcotic. According to the Pharmacy, the patient questioned the Tech as to why her other prescription wasn't ready, and after being informed, she began to raise her voice loud enough for others to hear her. On 12/5/2014, at Pharmacy 0744, patient alleged that Pharmacy yelled out medications in front of other customers on two separate occasions. Pharmacy Manager and floater indicated they spoke in low voice and the video shows the nearest customer as 10-12 feet away.

As to training, 10 out 420 associates had not completed HIPAA Privacy and Security training within 2 weeks of hire, or 2.38%, within goal. There were no government agency violations for unauthorized disclosure of PHI.

There were no pharmacies with a complaint filed against them by a State agency where probable cause was found.

As to the number of Florida technicians who did not have job class training within 180 days of hire, there were 3 out 101, or 2.97%, who had not completed the training, within goal. There were 2 out of 1,091 Pharmacy associates that had not completed annual renewal fraud and abuse training, or 0.18%, within goal. There were 21 out of 411 associates that had not completed Fraud, Waste and Abuse training within 1 week of hire, or 5.12%, a moderate hazard. There were 14 out of 420 associates that had not completed Methguard CBT within 1 week of hire, or 3.33%, within goal. Jillanne worked with ETD to obtain accurate reporting for the quarter, which may not have been so accurate in prior quarters.

In a random sampling taken in the 3<sup>rd</sup> quarter of Medicaid prescriptions, 2 out of 100 prescriptions sampled were not written on tamper resistant prescription pad, a moderate hazard. Corrective action was taken when the Pharmacy Supervisor reviewed the audit results with the pharmacists responsible for filling the prescriptions. It was discussed that there was a 6 year statute of limitations on actions for false claims regarding tamper resistant prescription pads. It was also discussed that Federal agencies could extrapolate non-compliance found in a few locations to all locations, and claim a 2%+ refund of all Medicaid prescriptions, plus treble damages. Recommended that the system be improved to require the pharmacist to key in yes or no to whether the prescription had been filled on a tamper resistant prescription pad.

The Team then discussed the annual risk assessment and the Pharmacy Risk Assessment Matrix. The attached Matrix was completed at the meeting, with all of the hazards assessed for severity and probability. The Team identified two new hazards, including failure of pharmacy to obtain CLIA license failure to

*Pharmacy Compliance Team Meeting 4th Quarter 2014, 2/19/15, 3*

verify proper registration in Medicare for Part B &D prescriptions. All of the risks were determined to be low, based upon controls currently in place, so no new metrics were added. No benchmarks were established for the % of prescriptions with QRE, as this metric is not designed to inform the Team of any compliance issue.



To Pharmacy Compliance Team  
From Karl Zillgitt  
Date 11/10/15  
Subject Pharmacy Compliance Team Meeting 3<sup>rd</sup> Quarter 2015

---

#### **Introduction**

On Tuesday, November 10, 2015, at 1:00 p.m., I met with Jillanne Smith, Ashley Greathouse and Adam Maingot for the 3<sup>rd</sup> quarter, 2015 Pharmacy Compliance Team meeting. The purpose of the meeting was to determine the status of Publix's compliance with applicable laws and regulations. A copy of the Metrics for the 3<sup>rd</sup> quarter is attached.

---

#### **Discussion**

The first order of discussion was Publix's compliance under the Pharmacy Metrics. Under the first risk, the Team reported 0 known Customer Complaints, Board of Pharmacy inquiries or physician complaints of a misfill where no corresponding QRE was on file. There was a complaint filed by the Fla. Dept. of Health regarding the dispensing of Depakote EC instead of Depakote ER to a child. A QRE had been filed for this incident.

For the second metric, the percentage of prescriptions with a QRE was .012%, a decline from the last quarter and the trend continued to point downward.

There were no governmental agency violations for filing a false claim. There was one known episode of a pharmacy associate embezzling prescription drugs from the RX Analyzer Report. The incident involved a Pharmacy tech who skimmed pain killers and other drugs (Adderall) from the will call area. The pharmacist began monitoring the will call bins and noticed a couple of short prescriptions.

There were no Government agency investigations regarding Publix pharmacies and the loss of controlled substances. For the number of times a pharmacy requested at least two increases during the quarter of the pharmacy's controlled substance purchasing allocation as set by McKesson, 4 stores had requested two increases during the quarter, a severe hazard. Ashley reported that pharmacy sales were up dramatically, and the pharmacies involved had requested small increases in their allocation, which were far smaller than their demand required,



*Pharmacy Compliance Team Meeting 3rd Quarter 2015, 11/10/15, 2*

so they had to request a second increase. No corrective action was determined to be necessary.

There was 1 legitimate HIPAA customer complaints for unauthorized disclosure of PHI, within goal. The incident involved a pharmacist disclosing the medication name in front of the customer service manager during a conversation with the patient. The Pharmacy supervisor verbally counseled the pharmacist.

As to training, 5 out 324 associates had not completed HIPAA Privacy and Security training within 2 weeks of hire, or 1.54%, within goal. There were no government agency violations for unauthorized disclosure of PHI.

There were no pharmacies with a complaint filed against them by a State agency where probable cause was found.

As to the number of Florida technicians who were not registered within 180 days of hire, 25 out 146, or 17.12%, had not completed the training, a severe hazard. Jillanne advised that if associates were not registered within 180 days of becoming a pharmacy technician, they were removed from the Pharmacy, and either did not work or worked in other store areas. Ashley advised that most of these pharmacy techs had now reported that they had received the training.

There were 4 out of 434 Pharmacy associates that had not completed annual renewal fraud and abuse training, or .92%, within goal. There were 13 out of 332 associates that had not completed Fraud, Waste and Abuse training within 1 week of hire, or 4.01%, within goal. There were 6 out of 324 associates that had not completed Methguard CBT within 1 week of hire, or 1.85%, within goal.

In a random sampling taken in the 3<sup>rd</sup> quarter of Medicaid prescriptions, 1 out of 100 prescriptions sampled were not written on tamper resistant prescription pad, a moderate hazard. Jillanne advised that there was a new prompt on the Pharmacy Rx system to ask if the prescription was made on a tamper resistant prescription pad, and Pharmacists and Pharmacy techs were trained on what to look for in tamper resistant prescriptions.



To Pharmacy Compliance Team  
From Karl Zillgitt  
Date 2/19/16  
Subject Pharmacy Compliance Team Meeting 4<sup>th</sup> Quarter 2015

---

#### **Introduction**

On Friday, February 19, 2016, at 2:30 p.m., I met with Jillanne Smith, Ashley Greathouse, Andy Shaw and Adam Maingot for the 4<sup>th</sup> quarter, 2015 Pharmacy Compliance Team meeting. The purpose of the meeting was to determine the status of Publix's compliance with applicable laws and regulations. The Team also conducted a Risk Assessment and completed a Risk Assessment Matrix listing the hazards the company faced and assessing the risk associated with those hazards. A copy of the Metrics for the 4<sup>th</sup> quarter and the Risk Assessment are attached.

---

#### **Discussion**

The first order of discussion was Publix's compliance under the Pharmacy Metrics. Under the first risk, the Team reported 0 known Customer Complaints, Board of Pharmacy inquiries or physician complaints of a misfill where no corresponding QRE was on file. For the second metric, the percentage of prescriptions with a QRE was .012%, the same as the last quarter and the trend continued to point downward.

There were no governmental agency violations for filing a false claim. There were three episodes of a pharmacy associate embezzling prescription drugs. All three incidents involved a Pharmacy tech who embezzled Alprazolam, Zolpidem or Tramadol, and resulted in a discharge. The Team talked about an incident where a cashier used an old override code to place returns back on her debit card. Pharmacy has been reviewing existing override codes and deleting them from the system, but there are still a few out there.

There were no Government agency investigations regarding Publix pharmacies and the loss of controlled substances. For the number of times a pharmacy requested at least two increases during the quarter of the pharmacy's controlled substance purchasing allocation as set by McKesson, \_\_ stores had requested two increases during the quarter, a severe hazard. The Team discussed this metric and agreed that it was not a good measure for measuring illegal dispensing of

*Pharmacy Compliance Team Meeting 4th Quarter 2015, 2/19/16, 2*

controlled substances. Adam advised that there was a new SOM system in place that flags orders of 5,000 controlled substances or multiple frequent orders of controlled substances, and then reports to DEA those orders that are determined to be suspect. The Team agreed to change this metrics to “# of suspicious orders of controlled substances reported to DEA through the SOM system”.

As to the # of legitimate HIPAA customer complaints for unauthorized disclosure of PHI, Adam promised to send out a list of questionable scenarios and the team would vote on whether these appeared to be legitimate HIPAA complaints, assuming the facts alleged are true. These would then be counted and input into the minutes.

As to training, 2 out 347 associates had not completed HIPAA Privacy and Security training within 2 weeks of hire, or .58%, within goal. There were no government agency violations for unauthorized disclosure of PHI.

There were no pharmacies with a complaint filed against them by a State agency where probable cause was found.

As to the number of Florida technicians who were not registered within 180 days of hire, 30 out of 98, or 30.61%, had not completed the training, a severe hazard. Jillanne advised that if associates were not registered within 180 days of becoming a pharmacy technician, they were removed from the Pharmacy, and either did not work or worked in other store areas. The Team discussed requiring new techs to sign an agreement prior to starting that would be signed by the Pharmacy tech. and by the manager requiring the tech to take the training court and register within 180 days of hire, or the associate would be terminated. The Team also talked about flagging the Pharm. Techs who had not registered within so many months after hire, or after receiving training, and a notification could be sent to the managers to remind them to require their techs to register.

0 out of 434 Pharmacy associates had not completed annual renewal fraud and abuse renewal training, or .0%, within goal. There were 10 out of 225 associates that had not completed Fraud, Waste and Abuse training within 1 week of hire, or 2.90%, within goal. There were 10 out of 345 associates that had not completed Methguard CBT within 1 week of hire, or 2.88%, within goal.

In a random sampling taken in the 4<sup>th</sup> quarter of Medicaid prescriptions, 1 out of 100 prescriptions sampled were not written on tamper resistant prescription pad (1%), a moderate hazard. Jillanne advised that there was a new prompt on the Pharmacy Rx system to ask if the prescription was made on a tamper resistant prescription pad, and this prompt was currently active.

The Team then discussed the annual risk assessment and the Pharmacy Risk Assessment Matrix. The attached Matrix was completed at the meeting, with all of the hazards assessed for severity and probability. The Team identified some new hazards, including failure of pharmacy to obtain CLIA license failure to verify proper registration in Medicare for Part B & D prescriptions. All of the risks were determined to be low, based upon controls currently in place, so no new metrics were added. No benchmarks were established for the % of prescriptions with QRE, as this metric is not designed to inform the Team of any compliance issue. The Team had to schedule a follow-up meeting to complete the Risk Assessment.

*Pharmacy Compliance Team Meeting 4th Quarter 2015, 2/19/16, 3*



To Pharmacy Compliance Team  
From Karl Zillgitt  
Date 4/29/16  
Subject Pharmacy Compliance Team Meeting 1<sup>st</sup> Quarter 2016

---

**Introduction**

On Friday, April 29, 2016, at 9:00 a.m., I met with Fred Ottolino, Jillanne Smith, Ashley Greathouse, Andy Shaw, Mike Hernandez and Adam Maingot for the 1<sup>st</sup> quarter, 2016 Pharmacy Compliance Team meeting. The purpose of the meeting was to determine the status of Publix's compliance with applicable laws and regulations. A copy of the Metrics for the 1<sup>st</sup> quarter is attached.

---

**Discussion**

The first order of discussion was Publix's compliance under the Pharmacy Metrics. Under the first risk, the Team reported 0 known Customer Complaints, Board of Pharmacy inquiries or physician complaints of a misfill where no corresponding QRE was on file. For the second metric, the percentage of prescriptions with a QRE was .012%, the same as the last quarter and the trend continued to point downward.

There were no governmental agency violations for filing a false claim. There was one episode of a pharmacy associate embezzling prescription drugs. The incident involved a Pharmacy tech who embezzled Tylenol 3 with codeine, and resulted in a discharge. Fred asked why it took Loss Prevention 3 weeks between the sting operation the associate being interview and ultimately discharged.

There were no Government agency investigations regarding Publix pharmacies and the loss of controlled substances. For the new metric "# of suspicious orders reported to DEA through SOM system", there were none. Fred asked if the SOM system was even in place and implemented, and Adam advised that there was a current system in place for schedule 3-5 substances. Now that the warehouse was distributing schedule 2 drugs, new software was purchased and was being piloted, and would become fully implemented at some point in the future.

As to the # of legitimate HIPAA customer complaints for unauthorized disclosure of PHI, Adam provided a list of questionable scenarios and the team voted on whether these appeared to be legitimate HIPAA complaints. The Team reviewed a case where a customer was concerned that the pharmacy released

*Pharmacy Compliance Team Meeting 1st Quarter 2016, 4/29/16, 2*

information about medication to the customer's mother. The Team discussed the current HIPAA training and whether it covered the scenario of adult children and sensitive medications, and determined that there was content covering this topic. I advised that Publix should have a written policy as well corresponding to its training, and Fred asked Jillanne to create such a policy for the R&P Guide.

As to training, 8 out of 361 associates had not completed HIPAA Privacy and Security training within 2 weeks of hire, or 2.22%, within goal. There were no government agency violations for unauthorized disclosure of PHI.

There were no pharmacies with a complaint filed against them by a State agency where probable cause was found.

As to the number of Florida technicians who were not registered within 180 days of hire, 24 out of 97, or 24.74%, had not completed the training, a severe hazard. Jillanne advised that if associates were not registered within 180 days of becoming a pharmacy technician, they were removed from the Pharmacy. If they were of a Pharmacy job class, they were not allowed to be scheduled for work in the Pharmacy. If they were classified in another job class outside of the Pharmacy, their access to the RX system was removed. This system to block associates from the Pharmacy if they did not register was implemented in March, and so the Team agreed that we needed to see how this corrective action would actually work before doing anything further.

61 out of 7171 Pharmacy associates or 0.85% had not completed annual renewal fraud and abuse renewal training, within goal. There were 35 out of 383 associates that had not completed Fraud, Waste and Abuse training within 1 week of hire, or 9.14%, a moderate hazard. Fred was looking at an initiative to require associates to take the training on day 1 after hire. The Team decided to wait and see what the reporting results were next quarter. There were 12 out of 361 associates that had not completed Methguard CBT within 1 week of hire, or 3.32%, within goal.

In a random sampling taken in the 1<sup>st</sup> quarter of Medicaid prescriptions, 0 out of 100 prescriptions sampled were not written on tamper resistant prescription pad (0%).



To Pharmacy Compliance Team  
From Karl Zillgitt  
Date 7/22/16  
Subject Pharmacy Compliance Team Meeting 2<sup>nd</sup> Quarter 2016

---

**Introduction**

On Friday, July 22, 2016, at 8:30 a.m., I met with Fred Ottolino, Jillanne Smith, Ashley Greathouse, Mike Hernandez and Adam Maingot for the 2<sup>nd</sup> quarter, 2016 Pharmacy Compliance Team meeting. The purpose of the meeting was to determine the status of Publix's compliance with applicable laws and regulations. A copy of the Metrics for the 2<sup>nd</sup> quarter is attached.

---

**Discussion**

The first order of discussion was Publix's compliance under the Pharmacy Metrics. Under the first risk, the Team reported 0 known Customer Complaints, Board of Pharmacy inquiries or physician complaints of a misfill where no corresponding QRE was on file. For the second metric, the percentage of prescriptions with a QRE was .013%, about the same as the last quarter and the trend continues to point downward.

There were no governmental agency violations for filing a false claim. There were 5 episodes of a pharmacy associate embezzling prescription drugs. One incident involved a Pharmacy manager who embezzled multiple scheduled drugs over a lengthy period of time, was discharged, arrested and faces significant jail time. Fred believes that incidents like the above could be avoided if the POs system were integrated with the Enterprise Rx system so that payment for the prescriptions could be verified and manipulation would be more difficult. Fred asked for this integration in 2006, but the project has never achieved tiered status. Adam will discuss this with Merriann.

There was one Government agency investigation regarding a Publix pharmacist and the loss of controlled substances, it relates to the embezzlement episode described above. For the new metric "# of suspicious orders reported to DEA through SOM system", there were none. I asked if the SOM system was covering schedule 2 drugs, and Adam advised that it was. Fred stated that there were controls in place to make sure that associates didn't use different distributors to obtain the same scheduled drugs.

*Pharmacy Compliance Team Meeting 2nd Quarter 2016, 7/22/16, 2*

As to the # of legitimate HIPAA customer complaints for unauthorized disclosure of PHI, Adam provided a list of questionable scenarios and the team voted on whether these appeared to be legitimate HIPAA complaints. The Team reviewed the cases and determined that there were 2, within goal. There was case where a customer was concerned that the pharmacy tech had accessed the file to obtain his personal phone and address to make threatening phone calls to his wife's cell number. He filed a police report. The tech was interviewed and admitted to some of the accusation, but was only counseled. Fred asked that this event be investigated and appropriate action taken. There was also a complaint where a customer pulled the label off of a 2007 prescription only to find another label with another customer's information. She would not release the bottle to the Pharmacy Supervisor when contacted. Fred advised that the Pharmacy Supervisor should follow up with the customers on all complaints and then provide an updated report to Pharmacy management so that the Pharmacy Compliance Team has better facts from which to determine whether a HIPAA violation occurred.

As to training, 5 out 420 associates had not completed HIPAA Privacy and Security training within 2 weeks of hire, or 1.19%, within goal. There were no government agency violations for unauthorized disclosure of PHI.

There were no pharmacies with a complaint filed against them by a State agency where probable cause was found.

As to the number of Florida technicians who were not registered within 180 days of hire, 9 out of 118, or 7.63%, had not completed the training, a moderate hazard. The Team agreed to continue to wait and see how corrective action implemented in Q4 of last year would actually work before doing anything further.

4 out of 557 Pharmacy associates or 0.73% had not completed annual renewal fraud and abuse renewal training, a moderate hazard. This was monitored weekly, and supervisors get reports weekly, allowing the supervisors' administrators to track down associates that had not completed training. There were 18 out of 395 associates that had not completed Fraud, Waste and Abuse training within 1 week of hire, or 4.56%, within goal. There were 9 out of 420 associates that had not completed Methguard CBT within 1 week of hire, or 2.14%, within goal.

In a random sampling taken in the 2<sup>nd</sup> quarter of Medicaid prescriptions, 0 out of 100 prescriptions sampled were not written on tamper resistant prescription pad (0%).





To Pharmacy Compliance Team  
From Karl Zillgitt  
Date 4/28/17  
Subject Pharmacy Compliance Team Meeting 1<sup>st</sup> Quarter 2017

---

#### **Introduction**

On Friday, April 28, 2017, at 1:30 p.m., I met with Jillanne Smith, Fred Ottolino, Ashley Greathouse, Michael Hernandez, Jessica Shaw and Adam Maingot for the 1<sup>st</sup> quarter, 2017 Pharmacy Compliance Team meeting. The purpose of the meeting was to determine the status of Publix's compliance with applicable laws and regulations. A copy of the Metrics for the 1<sup>st</sup> quarter are attached.

---

#### **Discussion**

The first order of discussion was Publix's compliance under the Pharmacy Metrics. Under the first risk, the Team reported 0 known Customer Complaints, Board of Pharmacy inquiries or physician complaints of a misfill where no corresponding QRE was on file. For the second metric, the percentage of prescriptions with a QRE was .010%, a decrease from the last quarter and the trend continues to point downward.

There were no governmental agency violations for filing a false claim. There were 2 episodes of a pharmacy associate embezzling prescription drugs. There were no Government agency investigations regarding a Publix pharmacist or pharmacy and the loss of controlled substances. For the new metric "# of suspicious orders reported to DEA through the SOM system", there were none. The Team discussed a recent Administrative Law Judge opinion regarding wholesaler responsibilities in monitoring the SOM system that may affect upcoming DEA Guidance.

As to the # of legitimate HIPAA customer complaints for unauthorized disclosure of PHI, Adam provided a list of questionable scenarios and the team voted on whether these appeared to be legitimate HIPAA complaints. The Team reviewed the cases and determined that there were no legitimate HIPAA complaints, within goal.

As to training, 12 out 399 associates had not completed HIPAA Privacy and Security training within 2 weeks of hire, or 3.01%, within goal. There were no government agency violations for unauthorized disclosure of PHI. There was

*Pharmacy Compliance Team Meeting 1st Quarter 2017, 4/28/17, 2*

one pharmacy with a complaint filed against it by a State agency where probable cause was found. The matter was settled with a \$5,000 fine.

As to the number of Florida technicians who were not registered within 180 days of hire, 3 out of 88, or 3.41%, had not completed the training, within goal.

7 out of 374 Pharmacy associates or 1.87% had not completed annual renewal fraud and abuse renewal training, a moderate hazard. This was monitored weekly, and supervisors get reports weekly, allowing the supervisors' administrators to track down associates that had not completed training. There were 24 out of 390 associates that had not completed Fraud, Waste and Abuse training within 1 week of hire, or 6.51%, a moderate hazard. The Pharmacy Dept. receives a weekly report, which shows in red the associates that have not taken the training. Follow up by the Pharmacy Dept. results in the associates taking the training. There were 15 out of 399 associates that had not completed Methguard CBT within 1 week of hire, or 3.76%, within goal.

In a random sampling taken in the 4<sup>th</sup> quarter of Medicaid prescriptions, 0 out of 100 prescriptions sampled were not written on tamper resistant prescription pad.



To Pharmacy Compliance Team  
From Karl Zillgitt  
Date 11/3/17  
Subject Pharmacy Compliance Team Meeting 3<sup>rd</sup> Quarter 2017

---

#### **Introduction**

On Wednesday, August 2<sup>nd</sup>, 2017, at 3:00 p.m., I met with Jillanne Smith, Ashley Greathouse, Michael Hernandez, Jessica Shaw, Candin Ruvolo and Adam Maingot for the 3<sup>rd</sup> quarter, 2017 Pharmacy Compliance Team meeting. The purpose of the meeting was to determine the status of Publix's compliance with applicable laws and regulations. A copy of the Metrics for the 3<sup>rd</sup> quarter are attached.

---

#### **Discussion**

The first order of discussion was Publix's compliance under the Pharmacy Metrics. Under the first risk, the Team reported 0 known Customer Complaints, Board of Pharmacy inquiries or physician complaints of a misfill where no corresponding QRE was on file. For the second metric, the percentage of prescriptions with a QRE was .008%, a decrease from the last quarter and the trend continues to point downward.

There were no governmental agency violations for filing a false claim. There were 3 episodes of a pharmacy associate embezzling prescription drugs. Each of these incidents were discussed by the Team. A 4<sup>th</sup> incident was discussed involving a pharmacy manager processing cash refunds in the evening when the customers were not around through the use of a discount card. The Pharmacy Dept. agreed to conduct further research, but the incident was not included as an embezzlement.

There were no Government agency investigations regarding a Publix pharmacist or pharmacy and the loss of controlled substances. For the new metric "# of suspicious orders reported to DEA through the SOM system", there were none. However, the Team discussed the Masters case and the duty on Publix to create and retain documentation substantiating the reasons supporting an increase in the orders for scheduled drugs, and whether Publix is required to report to the DEA a notice of unusual purchasing activity in the SOM system even if it can document the reasonable explanations for such increases. Jillanne will meet with Chris Hewell about Publix's documentation process and then get with Adam.

*Pharmacy Compliance Team Meeting 3rd Quarter 2017, 11/3/17, 2*

As to the # of legitimate HIPAA customer complaints for unauthorized disclosure of PHI, Adam provided a list of complaints filed and indicated that one appeared to be a legitimate HIPAA complaint. Adam then advised that he believed we should only be reporting on HIPAA complaints that have been determined to be legitimate by the team (Melynda and Adam). Candin advised that there was a separate HIPAA Compliance Team, and the Team then discussed that these metrics should be used by the HIPAA Compliance Team. Thus, during the next risk assessment, it was discussed dropping the HIPAA metrics and allowing the HIPAA Compliance Team to assume responsibility for HIPAA related metrics. There were no government agency violations for unauthorized disclosure of PHI.

There were 3 pharmacies with a complaint filed against them by a State agency where probable cause was found. South Carolina had beefed up its audit process, and this resulted in a couple of complaints being filed with the South Carolina Bd. of Pharmacy. Adam also mentioned that 2 complaints had been filed on the prior quarter that had not been reported, which should have been reported. He will provide the details in an email.

As to training, 30 out 394 associates had not completed HIPAA Privacy and Security training within one weeks of hire, or 7.61%, a moderate hazard. This was due to Hurricane Irma.

6 out of 109 Pharmacy techs or 5.5% had not registered with the state within 180 days of entering the JC, a moderate hazard. All of the pharmacy techs that had not registered were removed from the pharmacy. 1 out of 138 Pharmacy associates or .72% had not completed annual renewal fraud and abuse renewal training, a moderate hazard. There were 50 out of 394 associates that had not completed Fraud, Waste and Abuse training within one week of hire, or 12.69%, a severe hazard. There were 29 out of 394 associates that had not completed Methguard CBT within one week of hire, or 7.36%, a moderate hazard. The last two moderate hazards were the result of Hurricane Irma. Follow up by the Pharmacy Dept. resulted in all overdue associates taking the training.

In a random sampling taken in the 3<sup>rd</sup> quarter of Medicaid prescriptions, 0 out of 100 prescriptions sampled were not written on tamper resistant prescription pad.



To Pharmacy Compliance Team  
From Karl Zillgitt  
Date 8/2/17  
Subject Pharmacy Compliance Team Meeting 2<sup>nd</sup> Quarter 2017

---

#### **Introduction**

On Wednesday, August 2<sup>nd</sup>, 2017, at 3:30 p.m., I met with Jillanne Smith, Ashley Greathouse, Michael Hernandez, Jessica Shaw and Adam Maingot for the 2<sup>nd</sup> quarter, 2017 Pharmacy Compliance Team meeting. The purpose of the meeting was to determine the status of Publix's compliance with applicable laws and regulations. A copy of the Metrics for the 2<sup>nd</sup> quarter are attached.

---

#### **Discussion**

The first order of discussion was Publix's compliance under the Pharmacy Metrics. Under the first risk, the Team reported 0 known Customer Complaints, Board of Pharmacy inquiries or physician complaints of a misfill where no corresponding QRE was on file. For the second metric, the percentage of prescriptions with a QRE was .008%, a decrease from the last quarter and the trend continues to point downward.

There were no governmental agency violations for filing a false claim. There were 3 episodes of a pharmacy associate embezzling prescription drugs. Each of these incidents were discussed by the Team. There were no Government agency investigations regarding a Publix pharmacist or pharmacy and the loss of controlled substances. For the new metric "# of suspicious orders reported to DEA through the SOM system", there were none. The Team discussed the recent 11<sup>th</sup> Circuit case affirming an Administrative Law Judge opinion imposing certain wholesaler responsibilities in monitoring the SOM system, including the creation and retention of documentation substantiating the reasons supporting an increase in the orders for scheduled drugs, and whether pharmacies are required to file with the DEA a notice of unusual purchasing activity in the SOM system even if they can document the reasonable explanations for such increases. Adam will find out from Chris what Publix is documenting to date, and make Chris aware of our substantiation requirements. Adam will also inquire with NACDS and our outside counsel what other pharmacies are doing regarding the filing obligation with DEA.

*Pharmacy Compliance Team Meeting 2nd Quarter 2017, 8/2/17, 2*

As to the # of legitimate HIPAA customer complaints for unauthorized disclosure of PHI, Adam provided a list of complaints filed and indicated that none of them appeared to be legitimate HIPAA complaints, although he was still following up on one compliant. There were no government agency violations for unauthorized disclosure of PHI. There were four pharmacies with a complaint filed against them by a State agency where probable cause was found. Two resulted in fines of \$2,500 each.

As to training, 7 out 407 associates had not completed HIPAA Privacy and Security training within 2 weeks of hire, or 1.72%, within goal.

8 out of 106 associates or 7.55% of the Pharmacy techs failed to register with the state within 180 days of entering the JC. All of the pharmacy techs that had not registered were removed from the pharmacy.

0 out of 91 Pharmacy associates or 0% had not completed annual renewal fraud and abuse renewal training, within goal. There were 24 out of 381 associates that had not completed Fraud, Waste and Abuse training within 1 week of hire, or 6.30%, a moderate hazard. The Pharmacy Dept. receives a weekly report, which shows in red the associates that have not taken the training. Follow up by the Pharmacy Dept. results in the associates taking the training. The Team discussed changing the metric to measure after 90 days of hire, as 90 days was the statutory requirement. This was agreed to, and the benchmarks were changed to "Goal: 0". There were 6 out of 407 associates that had not completed Methguard CBT within 1 week of hire, or 1.47%, within goal.

In a random sampling taken in the 2<sup>nd</sup> quarter of Medicaid prescriptions, 0 out of 100 prescriptions sampled were not written on tamper resistant prescription pad.



To Pharmacy Compliance Team  
From Karl Zillgitt  
Date 7/31/18  
Subject Pharmacy Compliance Team Meeting 2<sup>nd</sup> Quarter 2018

---

#### **Introduction**

On Tuesday, July 31<sup>st</sup>, 2018, at 3:30 p.m., I met with Jillanne Smith, Toan Do, David Kirkus, Jennifer Warren, Michael Hernandez, Bill Howard, Candin Ruvolo, Toni Hiers, Dain Rusk and Adam Maingot for the 2<sup>nd</sup> quarter, 2018 Pharmacy Compliance Team meeting. The purpose of the meeting was to determine the status of Publix's compliance with applicable laws and regulations. A copy of the Metrics for the 2<sup>nd</sup> quarter are attached.

---

#### **Discussion**

The first order of discussion was Publix's compliance under the Pharmacy Metrics. Under the first risk, the Team reported 0 known Customer Complaints, Board of Pharmacy inquiries or physician complaints of a misfill where no corresponding QRE was on file. For the second metric, the percentage of prescriptions with a QRE was .009%, the same as last quarter and the trend continues to point downward.

There were no governmental agency violations for filing a false claim. There were 3 episodes of a pharmacy associate embezzling prescription drugs. The incident discussed by the Team involved a Pharmacy tech who rang a prescription through under another customers name, and failed to provide the receipt to that customer so that the customer would not know he was issued 5 prescriptions instead of 4. Pharmacy discovered the error because the customer who should have received the Oxycodone complained and was reissued the prescription. The incident was reported to DEA on Form 106, and the insurance claim was not reversed because the patient did receive their medication. There were HIPAA concerns because the patients information was on the bottle that was stolen. Bill agreed to talk with Heather Dudman to obtain any cases where a Pharmacy interview reveals employee embezzlement of prescription drugs.

There were 3 Government agency investigations regarding a Publix pharmacy or Pharmacy personnel and controlled substances. Two did not appear to be focused on the Pharmacy, but on the patients receiving the medications. The FBI was investigating South Florida pharmacies that issued drugs to patients involved

*Pharmacy Compliance Team Meeting 2nd Quarter 2018, 7/31/18, 2*

in a widespread sting operation. It does not appear that the pharmacists were in cahoots with the perpetrators (doctors/patients). However, there were scripts with missing information, such as the physician's DEA # and there is also evidence that Publix did not fill some prescriptions because of red flags. The FBI agent has stated that he doesn't believe Publix was complicit, but the community pharmacies may have been complicit.

For the metric "# of suspicious orders reported to DEA through the SOM system", there were none. However, the Team discussed the Suspicious order monitoring system and believes it does not work. All of the algorithms (red flags) that can be triggered on the system have been shut down except for 2 relating to the size of the order, so that only a couple of orders were stopped last year. Vendor does not want to work with Publix in making their program work on Publix's system. Also, even if an order were stopped by the Suspicious ordering system, the store could simply purchase the drugs from the wholesaler. Thus, the Team believed that this metric should be removed.

There were no pharmacies with a complaint filed against them by a State agency where probable cause was found. The Team discussed what this metric should produce, and it was determined that Publix should be reporting any notices of violation from a State or Federal agency.

7 out of 198 Pharmacy techs or 3.54% had not registered with the state within 180 days of entering the JC, within goal. All of the pharmacy techs that had not registered were removed from the pharmacy. 3 out of 679 Pharmacy associates or .44% had not completed annual renewal fraud and abuse renewal training, within goal. Jillanne advised that Fraud, Waste & Abuse data in Learning was not accurate, as there were a lot more Pharmacy associates being trained than what was being reported by the system. There were 4 out of 395 associates that had not completed Fraud, Waste and Abuse training within 45 days of hire, or 1.01%, within goal. There were 13 out of 395 associates that had not completed Methguard CBT within one week of hire, or 1.01%, within goal.

In a random sampling taken in the 1<sup>st</sup> quarter of Medicaid prescriptions, 0 out of 100 prescriptions sampled were not written on tamper resistant prescription pad.

Finally, Dain advised that he had not confidence that we were measuring the right metrics where we had the greatest risk. Thus, I advised that we should conduct another risk assessment, and emailed Candin Ruvolo to see if we can commence a Risk Assessment under the new program. Thus, the Q3 meeting will be rescheduled with more time to complete the Risk Assessment.